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Award Number: DAMD17-94-J-4360

TITLE: Facility Inreach Strategy to Promote Annual Mammography

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REPORT DATE: October 1999

TYPE OF REPORT: Final

PREPARED FOR: U.S. Army Medical Research and Materiel Command  
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for public release  
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**DTIC QUALITY INSPECTED 4**

**20001013 128**

# REPORT DOCUMENTATION PAGE

Form Approved  
OMB No. 074-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503

<b>1. AGENCY USE ONLY (Leave blank)</b>		<b>2. REPORT DATE</b> October 1999	<b>3. REPORT TYPE AND DATES COVERED</b> Final (01 Oct 94 - 30 Sep 99)	
<b>4. TITLE AND SUBTITLE</b> Facility Inreach Strategy to Promote Annual Mammography			<b>5. FUNDING NUMBERS</b> DAMD17-94-J-4360	
<b>6. AUTHOR(S)</b> Joni Mayer, Ph.D.				
<b>7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)</b> San Diego State University Foundation San Diego, California 92182-1900  e-mail: jmayer@mail.sdsu.edu			<b>8. PERFORMING ORGANIZATION REPORT NUMBER</b>	
<b>9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)</b> U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012			<b>10. SPONSORING / MONITORING AGENCY REPORT NUMBER</b>	
<b>11. SUPPLEMENTARY NOTES</b>				
<b>12a. DISTRIBUTION / AVAILABILITY STATEMENT</b> Approved for public release distribution unlimited				<b>12b. DISTRIBUTION CODE</b>
<b>13. ABSTRACT (Maximum 200 Words)</b>  The purpose of this study was to increase annual return rates for screening mammography among asymptomatic women 50 - 74 years. The study tested the effectiveness of a physician endorsed reminder letter relative to a standard mammography facility reminder letter and to no intervention. Six mammography facilities and 82 referring physicians participated. Physician participation rates ranged from 35-67% across facilities. Over the course of the 23 month recruitment period, 3,701 eligible women were approached and 1,971 (53%) of those consented to participate. Of the 1,971 consenting women, 108 women subsequently had positive mammograms and were excluded from the study, leaving 1,863 subjects. Subjects were interviewed by phone regarding knowledge, attitudes, and behaviors related to mammography. Overall, 1,818 telephone interviews were completed. Primary outcome data were available for 1,562 subjects. Forty-eight percent of subjects in the physician endorsed group returned within the 8-week monitoring period, 47% in the standard facility group, and 28% in the control group; the overall difference among return rates was significant ( $p < 0.001$ ). Bonferroni pairwise comparisons indicated there was no difference between the physician endorsed and standard facility groups. However, both of these groups had significantly higher return rates than the control group.				
<b>14. SUBJECT TERMS</b> Mammography, Adherence, Breast Cancer, Inreach, Screening Guidelines				<b>15. NUMBER OF PAGES</b> 128
				<b>16. PRICE CODE</b>
<b>17. SECURITY CLASSIFICATION OF REPORT</b> Unclassified	<b>18. SECURITY CLASSIFICATION OF THIS PAGE</b> Unclassified	<b>19. SECURITY CLASSIFICATION OF ABSTRACT</b> Unclassified	<b>20. LIMITATION OF ABSTRACT</b> Unlimited	

NSN 7540-01-280-5500

Standard Form 298 (Rev. 2-89)  
Prescribed by ANSI Std. Z39-18  
298-102

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10-12-99  
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## 5. INTRODUCTION

Breast cancer is the most prevalent type of cancer and the second leading cause of cancer-related mortality in American women (1). Results from large scale trials have shown a decrease in breast cancer mortality by up to 33% in women aged 50 and older (2). The American Cancer Society (ACS), and other agencies have recommended annual mammograms for women 50 and older. However, at the time this study was proposed, adherence to the screening guidelines needed to reduce breast cancer mortality was low (3-8). In the four studies that examined the rates and correlates of interval adherence, the rates of "more than 1" mammogram for women 50+ were 23%, 34%, 45%, and 47% (5-8). In all studies, physician recommendation consistently predicted repeat screening. Reminder letters had been successful in promoting general mammography appointment adherence (9) and cervical screening appointment adherence (10,11) relative to no letters. In the area of mammography adherence, there was a lack of trials to evaluate reminder strategies using true control groups and focusing on interval adherence. Because of the importance of physician recommendation as a facilitator in mammography interval adherence, incorporating the physician's endorsement of screening in a reminder strategy appeared warranted. The primary purpose of this study was to increase annual return rates for screening mammography among asymptomatic women aged 50 and older. Specific project objectives were: a) to develop an intervention aimed at promoting return mammogram adherence within 12-14 months following the last mammogram consisting of a reminder letter mailed by the mammography facility but originating from the referring physician; b) to refine and standardize a comparison reminder letter; c) to implement and monitor the proposed interventions at six mammography facilities in San Diego, California; and d) to evaluate the effectiveness of the primary care physician's letter in increasing return mammogram adherence relative to the "standard" facility letter and to no intervention. The study used a three group, randomized design with subjects randomized from within referring physician within mammography facility. We hypothesized that the physician letter would produce significantly higher adherence than the standard letter, and that the standard letter would produce significantly higher adherence than no letter. A secondary purpose was to increase the understanding of the factors that influence interval adherence to mammography. Specific objectives relevant to this goal were: a) to assess via a phone interview selected demographic, psychosocial, health-related, health services, and mammography-experience related variables within approximately 4-8 weeks after a screening mammogram; and b) to evaluate prospectively relationships between these variables and subsequent mammogram adherence, controlling for study condition.

## 6. BODY

### Experimental Methods

#### Overview of Project

The study used a randomized three-group design to compare the effects of two interventions and a control condition on annual return rates to mammography facilities for screening mammograms by women 50-74 years. The treatments included a) delayed appointment reminder (control), b) "standard" reminder -- appointment reminder from the facility that provided last year's mammogram, and c) physician endorsement reminder -- appointment with physician's prompt to patient to have an annual mammogram at the facility.

Study procedures were as follows for subjects in a given wave: a) potential subjects were approached by the project at or around the time of the study entry mammogram; b) subject consent forms were completed and collected; c) verification was made that the entry mammogram had negative results; d) the interview was conducted within approximately 8 weeks of the study entry mammogram; e) approximately eleven months after being recruited, subjects were randomly assigned to groups; f) for subjects in the standard reminder and physician endorsement reminder groups, reminder letters were mailed the day before the first day of the targeted appointment month; g) staff monitored facility appointment records to evaluate return rates of subjects within 60 days (of day 1) of the targeted appointment month; h) reminder letters were mailed to control group subjects on the last day of the 60 day monitoring period. Staff monitored facility appointment records to evaluate return rates of subjects within 6 months (of day 1) of the targeted appointment month.

Measurement procedures consisted of a) a 43 item telephone interview within approximately 4-8 weeks following the study entry mammogram to obtain information on demographic characteristics, mammography history, perceptions of the mammography experience, selected health history, knowledge of mammography guidelines, health beliefs specific to breast cancer and mammography, intentions to have a subsequent annual mammogram, self-efficacy for obtaining annual mammography, and access to medical care; b) monitoring facility appointment records to evaluate return rates of subjects within 60 days (of day 1) of the targeted appointment month; and c) monitoring facility appointment records to evaluate return rates of subjects within 6 months (of day 1) of the targeted appointment month.

We originally planned to conduct the study at four mammography facility sites (called "original sites"). After several months of subject recruitment at the original sites, we determined that we would not be able to reach the required sample size and decided to recruit two additional facilities. Two additional facilities were recruited during the grant year 1995-1996. Random assignment of subjects to groups occurred within each facility and each referring physician. In order to achieve the final sample size of 1,560 subjects

(520 per group), subject recruitment was extended through April, 1997. A total of 1,863 subjects were recruited. The interviews and intervention were implemented in a staggered manner, with each lasting approximately 23 months (with overlap).

### Strategies to Enhance Participation

The success of the project was dependent on adequate levels of participation by facilities, referring physicians, and subjects. Consequently, strategies for encouraging participation at each level were used. The research team included a general practitioner, Linda Hill, M.D., M.P.H., who provided consultation on the intervention from the referring physician's and patient's perspective and a radiologist, Charles Lee, M.D., J.D., who consulted on quality assurance of mammography and other facility-related issues. The input of these consultants helped assure that the intervention was acceptable to patients, referring physicians, and mammography providers.

### Study Facilities

Inclusion criteria for sites were: a) patient volume could accommodate approximately one-sixth of the sample; b) computerized or manual record keeping system appeared accurate and efficient; c) personnel at site agreed to follow study protocol (e.g., delay reminders for control group); d) facility was certified by the California Department of Health Services (CDHS) Radiologic Health Branch, was accredited by the American College of Radiology (ACR), and the Food and Drug Administration (FDA) e) facility used a fee-for-service model; and f) facility had been in business for at least one year prior to the study's onset.

Generally, facilities are very interested in improving patient services, enhancing relationships with referring physicians, and increasing their revenues. They were told that these were three potential benefits of participating in the study via the introductory packet we mailed. Initially, project staff sent facility directors a packet containing the following: an introductory cover letter, pilot study results, a sample of the physician-endorsed reminder letter, and a chart stating the responsibilities of participating facilities and the project staff (timeline for all activities included). Next, phone calls were placed and face to face meetings were held.

We completed recruitment of the four original sites in January, 1995. South Bay Radiology is located in the southern portion of the county (Chula Vista), has a high proportion of Latinas who primarily speak Spanish (approximately 50% of patient population), and performs 30-35 screening mammograms a day. The Alvarado Breast Center is located in central San Diego county, has a Caucasian, middle class patient population, and performs 15-20 screening mammograms a day. The UCSD Center for Women's Health is also located in central San Diego County, has a diverse patient population, and performs 10-15 screening mammograms a day. Our fourth original site, the Lybrand Mammography and Education Center at Scripps Memorial Hospital, is



located in northern San Diego county, has a primarily mid-upper income Caucasian patient population and performs 10-15 screening mammograms a day.

The second phase of facility recruitment was completed in March, 1996. Mercy Hospital Women's Imaging Center is located in central San Diego County, has a diverse patient population, and performs 10 screening mammograms a day. Tri-City Outpatient Imaging Center is located in the northwestern part of the county, has a primarily middle class patient population, and performs 20-30 screening mammograms a day.

Initial recruitment and continued participation by facilities was assisted by minimizing the burden on facility staff for data monitoring and intervention procedures. All procedures that involved the facility's assistance (e.g., data monitoring) were as efficient as possible and were coordinated with the facility's schedule. An initial annual meeting was held at each of the study facilities as a forum for facility and project staff to discuss study progress and share ideas for streamlining study procedures.

### Referring Physicians

Prior to the physician recruitment phase of the study, approximately 23 physicians were questioned to assess any concerns with the intervention procedures via one focus group and one conference exhibit (the conference was directed towards primary care physicians). The physicians who provided us with feedback did not have reservations about study procedures, and almost unanimously approved of our physician-endorsed reminder letter, commenting that it was short and to the point. Pilot study physicians also were contacted for feedback. Six physicians responded and all stated that their experience was positive and that they would participate again.

In obtaining the cooperation of referring physicians, facility staff assisted project staff. Facility staff identified 23-31 of the physicians who referred the most number of mammography patients to their facility. Project staff sent a packet containing the following: an introductory cover letter, letter of support from the facility medical director, pilot study results, a sample of the physician-endorsed reminder letter, and a chart stating the responsibilities of participating physicians and the project staff. In each packet was a self-addressed stamped envelope and form to be signed indicating the physician's participation. Follow-up calls were made until a response from each physician was obtained.

Physicians were encouraged not to modify their patient recall or referral patterns during the course of the study, nor to discuss the study with their patients. They were told they would be providing a blanket consent that potentially covers any of their referred patients who meet the other inclusion criteria. During physician recruitment, we reassured physicians that the control group would receive a reminder delayed by only 2 months. After a physician was recruited, project staff acquired the physician's stationery in an organized manner. During the subject recruitment phase (June 1995 - April 1997) physicians were sent a list of their patients participating in the study every few months.

At the end of subject recruitment a comprehensive list of patients recruited was sent to each physician. Physicians received copies of the letters that were sent to patients in the physician endorsement reminder group at the end of the intervention phase. Physician recruitment was completed in June, 1996.

### Subjects

Subjects were recruited in monthly waves over a 23-month period. Inclusion criteria were: a) age 50-74 (at the time of entry mammogram); b) no history of breast cancer; c) had routine screening mammogram at facility during the course of the study with negative test results; d) referring physician for entry mammogram agreed to the intervention protocol; e) consented to participate; and f) spoke either English or Spanish. Criterion c made the assumption that the woman was asymptomatic. Ongoing studies in progress in San Diego that confounded results of the present study were determined. Subjects who participated in the clinical arms of the Women's Health Initiative were excluded from the present study.

Prior to starting subject recruitment four focus groups were conducted with: African American women, Filipino/Caucasian women, Latinas, and Caucasian women. Questions were asked regarding telephone interview questions, the intervention letter, and subject recruitment strategies. Modifications to the telephone interview were made as a direct result of the feedback we received. For example, women objected to a series of questions regarding reasons for and timing of their three most recent mammograms. In the final version of the telephone interview, women were asked about only one of their prior mammograms. We were told repeatedly to keep the interview as short as possible. Another important finding was that women were split regarding preferences for introduction to the study by mailings versus in person - thus we attempted to reach all potential subjects by letter and phone before their mammography appointments. During the Latina focus group, wording/translations for medical terms like breast lump, clinical breast exam, and breast self-exam were clarified.

Participation rates of women in the study were maximized by: a) incorporating the recruitment and consent procedures into the mammography appointment and providing comprehensive training for the facility staff; b) both before and if necessary, after, the mammography appointment we contacted women by phone and/or mail to explain the project, c) employing mature, sensitive female interviewers who received comprehensive training, d) pilot testing the survey instrument and script for clarity, sensitivity, and duration and making necessary refinements, e) assuring confidentiality of responses, and f) for Latinas who preferred Spanish, providing Spanish language materials and a bilingual interviewer.

Subjects were recruited and written consent obtained near the time of the initial (entry) mammogram. Prior to this appointment, the appointment schedule containing information about inclusion criteria (e.g., physician consents, age, no breast cancer history) was highlighted. Research assistants attempted to reach all eligible subjects by

phone before their appointments to explain the project. At three facilities (UCSD, Lybrand, Tri-City) we had access to eligible women's addresses; packets (containing an introductory letter and consent forms) were mailed in addition to the phone calls. Every afternoon a list of eligible subjects due for mammograms the next day was faxed to each facility. Two times a week research assistants determined which women were eligible but did not fill out consent forms; these women were re-contacted by phone and if still willing to participate, were mailed another consent packet.

The facility receptionists and mammography technologists received training by project staff to: a) briefly describe the study to the potential subject before or after the appointment, b) encourage the patient to read a brief description of the project (available in Spanish and English), c) provide the consent form (Spanish and English) and address any questions or concerns, and d) obtain written consent and provide a copy of the form to the patient. Although the test results for the mammogram were not available at the appointment, obtaining consent at that time maximized participation rates and was efficient from a recruitment perspective. Patients whose test results subsequently were found to be positive or inconclusive were excluded as subjects. Women were included in the study if the interpreting radiologist recommended the next screening in one year. Potential subjects also were provided a self-addressed stamped envelope in case they preferred to read the information at home. Facility staffs' rates of recruitment and recruitment style were monitored by staff and feedback was given, as appropriate.

Subjects consented to participate in the study as a whole including a) the phone survey, b) random assignment to study conditions, and c) monitoring of mammography adherence. Women who refused survey participation at the time of the interview were dropped as subjects. One month prior to the targeted appointment month for a given wave, subjects in the wave (within referring physician within facility) were randomly assigned to one of the three study groups.

### Inclusion of Minorities

Because language may have been a barrier to participation in the study for San Diego's largest ethnic minority group, Latinos, two subject recruiters and two phone interviewers were bilingual in English and Spanish. The explanatory letter, consent form, and survey were translated into Spanish and Spanish-speaking women who were contacted for the survey had the choice of being interviewed in Spanish or English. Additionally, subjects who indicated a preference for Spanish in the interview received their intervention reminder letters in Spanish. Women who spoke neither English nor Spanish were excluded as subjects.

### Intervention Procedures

The intervention was implemented in monthly waves; the first wave of subjects was due for targeted mammograms in June, 1996. All subjects in a wave received their study entry mammogram during the same calendar month. In order to simplify the mailing and

monitoring procedures, the following occurred: a) the month of the subject's entry appointment was the designated month of the targeted appointment, irrespective of what day of the month it occurred; b) reminders were timed to arrive on or about day 1 of the targeted appointment month; c) the primary interval in which adherence was assessed for all subjects was 60 days, beginning with day 1 of the designated appointment month; and d) for secondary analysis, facility appointment records were monitored for an additional 4 months (6 months from day 1 of the targeted appointment month) for subject returns. The uniform mailing date for each wave dictated the uniform outcome monitoring period for each wave. The procedures for each study group are detailed below.

Group 1. The control group (within each facility and wave) received no reminder during the outcome monitoring period for that wave. However, after the interval, they received the "standard" (Group 2) reminder.

Group 2. These subjects received the standard reminder on the facility letterhead prior to the targeted appointment month, as described above. All participating facilities reached consensus on the wording of the standard facility reminder letter. The letter a) stated that it had been a year since the last mammogram, b) encouraged the patient to call her physician to schedule a clinical breast exam and obtain a mammography referral c) encouraged the patient to call for a mammography appointment, and d) provided the facility's name, address, and phone number. A sample of the standard facility reminder is attached (Appendix A).

Group 3. These subjects received the "physician endorsement" reminder letter on the referring physician's letterhead with his/her signature prior to the appointment month. In most cases the project purchased signature stamps to facilitate the timely mailings of the letters (some physicians decided to sign the letters). The content was the same as the standard reminder letter; the main difference was that the letter was from the physician rather than the facility. A sample of the physician endorsement reminder letter is also attached (Appendix B).

Project staff collected samples of the reminder letters used by the participating facilities as well as reminder letters used in similar studies. These samples were considered when drafting the final version of the reminder letters.

### Measures and Assessment Procedures

The primary sources of data were patient self-report (i.e., the pre-intervention survey) and archival records maintained by the facilities (i.e., patient appointment data for measuring outcome). The measures are described in detail in the following sections.

#### Pre-intervention Survey

Purpose and content. A telephone interview was conducted with subjects to obtain data for describing the sample and for developing models to predict subsequent

mammography adherence. The 43-item survey is attached (Appendix C). The items included:

- demographics: birthdate, education, ethnicity (and language preference, if Latina), marital status, employment status, income;
- provider variables: regular source of medical care, type of practice, is referring physician regular physician, specialty of referring physician;
- insurance coverage: type(s) of coverage;
- breast health history: previous breast complaint, previous breast cancer (exclude), previous biopsy, family history;
- screening history: total number of mammograms, dates of mammograms, reason for mammogram (diagnostic vs. screening), test results (if entry mammogram was diagnostic or had non-negative results, exclude), perceived screening pattern (e.g., sporadically, regularly-not annually, annually), perceived barriers (if not annually), perceived facilitators (if annually), ever had CBE, date of last CBE, reason for last CBE, perform BSE, BSE frequency;
- knowledge/beliefs: ACS mammography guideline for 50+, odds of any woman getting breast cancer, odds of subject getting it, age-related risk;
- intentions to have mammogram next year: likelihood in general, likelihood if doctor recommends;
- expectations for having mammogram next year: confidence in being able to schedule and complete the appointment (i.e., self-efficacy), confidence that annual screening will improve survival (i.e., outcome expectation);
- recent mammography experience: general satisfaction with experience, level of discomfort during compression.

Although women with a history of breast cancer or a non-negative study-entry mammogram were excluded based on facility records, items assessing these criteria were included in the survey as a safety measure. Facility records were used to generate basic demographic data for survey nonresponders (e.g., age). Additionally, all women who declined to participate during the recruitment call or telephone interview were asked to answer seven questions regarding demographics and reason(s) for not participating.

Information regarding the study inclusion mammogram was obtained from facility logs or records. History of mammograms prior to this relied on self-report. Self-report of mammography was found to be highly accurate in one study (12) and fairly accurate but overestimating the recency of the exam (i.e., exam was less recent than reported) in another study (13). Previous interval adherence was assessed by asking the number of previous mammograms obtained and by asking the subject to describe her pattern. The intervention outcome did not rely on self-report.

Subcontract for Telephone Interviews. We researched six research firms located in San Diego County and asked about their: specializations, interviewer selection process and training, quality control measures, data handling, cost, and references. After conducting informational interviews over the phone, we visited two of the firms. We determined that each firm had more resources to ensure the quality of the interviews than we would at our office and could conduct the interviews at a lower cost than that originally budgeted.

We chose to work with Luth Research, a firm with over 20 years of experience. Luth has a 50 line WATS phone facility supervised by up to three managers at a time. One supervisor walks around the room and listens to interviews in progress and one listens to interviews in progress and has the ability to edit the interview if he/she detects an interviewer error (unknown to the interviewee). Via modem, we had the ability to "listen" to interviews in progress as well. Luth Research uses Query software for their Computer-Assisted Telephone Interview (CATI) system. The CATI system guides interviewers through survey questions and allows them to enter data as women answer questions. The quality and efficiency of Luth's work for the project were excellent.

Procedures. For each subject at each site, the research assistants (R.A.s) generated a telephone interview cover sheet with a woman's phone number and most convenient time to call. Subjects were phoned at the time they specified as most convenient. A minimum of 20 attempts were made to contact each woman whose phone number appeared to be current, and attempts were made to update old numbers. If a woman refused to participate in or complete the interview once it began, she was thanked politely; no coercion was used.

The interviewer introduced herself and verified language preference and personal breast cancer history. After the introduction, the interviewer proceeded with the 20-minute interview. The interviewer entered information into the computer as each question was answered, clarifying questions as needed, using the CATI system. Interviewers kept records of completed calls, refusals, and call backs on telephone interview cover sheets provided by the project.

#### Measurement of Outcome

The dependent variable, mammography adherence, was assessed by the R.A.s from appointment records maintained at each facility. R.A.s were blind to subjects' study group assignment. The time frame monitored (for each wave) was 60 days, beginning on day 1 of the target appointment month. (Subjects in Groups 2 and 3 received their reminder letters immediately prior to this date). Appointment records also were used to determine if any subjects scheduled an appointment prior to intervention for either a screening or diagnostic mammogram; these subjects' data were deleted from the analysis. Adherence was coded dichotomously (yes, no) and required that the appointment be completed (i.e., both scheduled and kept) during the 60-day interval. Additionally,

records were monitored to determine whether subjects returned for a mammogram within 6 months of the first day of the targeted appointment month.

### Other Measures

Process data included: a) the number of facilities that were approached to reach the quota, b) cooperation rates of referring physicians, c) survey response rates, d) perceptions of facility staff about the intervention procedures, e) perceptions of cooperating referring physicians about the intervention, f) use of systematic reminder strategies (in addition to project's) by physicians, and g) study participation rates by subjects.

### Statistical Analysis

The primary hypothesis was that the physician endorsement letter would yield the highest adherence rate, followed by the standard letter, and no letter would yield the lowest rate. In addition to the analyses to evaluate this hypothesis, secondary analyses examined relationships between baseline demographic, psychosocial, health-related, health services, and mammography-experience related variables and subsequent mammogram adherence, controlling for study condition.

First, selected baseline variables were compared across the three groups to assess comparability. Chi-square tests for categorical variables and one-way analysis of variance for continuous variables were used. Because groups were comparable, a simple approach to assessing differences across adherence rates for all 1,562 subjects was to construct a 3x2 contingency table for the two categorical variables, study condition and adherence outcome, and use a chi-square test. Because the chi-square result was significant, pairwise contrasts were performed to assess specific differences using a Bonferroni adjustment. The CATMOD procedure in the SAS statistical package was employed.

For a more comprehensive analysis which yielded greater precision, we performed a multiple logistic regression where the outcome variable was adherence/non-adherence to the mammogram. This procedure allowed identification of important baseline variables that may predict adherence, consistent with the secondary goal of the study and, if necessary, adjustment for baseline variables in assessing differences among the study conditions for the survey completers. We also evaluated possible differences among the six radiology facilities and whether differences among study conditions varied by facility.

## Results

### Facility Recruitment

A total of 13 facility directors were approached and 6 (46%) of those agreed to participate in the study. Reasons for non-participation included: changes in the healthcare system (i.e., facility recently changed ownership/affiliation), facility already too busy/lack of resources, and low mammography screening volume.

### Physician Recruitment

At each facility, 23-31 of the most frequently referring physicians were identified by mammography facility staff. Physician participation rates varied across facilities: 67% at South Bay Radiology, 64% at UCSD Center for Women's Health, 48% at Lybrand Mammography and Education Center, 45% at Tri-City Medical Center, 45% at Alvarado Breast Center, and 35% at Mercy Hospital (see Table 1 below). Overall, 82 physicians participated in the study from various specializations: 25 (30%) Obstetrics/Gynecology, 23 (28%) Internal Medicine, 16 (20%) Family Practice, 6 (7%) General Practice, and 12 (15%) from other specializations. The most common reasons physicians cited for not participating in the study were: "too busy, no time" (even though we explained participation would require only 5-10 minutes total) and "not interested."

Table 1  
Referring Physician Recruitment Rates

Participation Status	Facility						All Facilities
	South Bay	UCSD	Lybrand	Alvarado	Mercy	Tri-City	
Participating	18 (67%)	16 (64%)	14 (48%)	14 (45%)	8 (35%)	12 (48%)	82 (51%)
Not Participating	9	9	15	17	15	13	78
Total Approached	27	25	29	31	23	25	160



## Subject Recruitment

Subject recruitment rates varied at the six facilities: 76% of eligible women consented at the Alvarado Breast Center, 62% at UCSD Center for Women's Health, 54% at Lybrand Mammography and Education Center, 50% at Tri-City Outpatient Imaging Center, and 36% at Mercy Hospital. At South Bay Radiology, 44% of English-surname eligible women consented while 19% of Spanish-surname women consented for an overall rate of 31% (see Table 2 below).

Over the course of the 23 month recruitment period, we identified and approached 3,701 eligible women. Of those women, 1,971 consented to participate in the study. Of the 1,971 consenting women, 108 women subsequently had positive mammograms and were excluded from the study, leaving 1,863 study subjects.

Table 2  
Subject Recruitment by Facility

Facility	Participation Status		
	# Eligible	# Consented	# Normal Mammograms (Study Subjects)
Facility 1: South Bay Radiology English Surname	399	175 (44%)	154
Facility 1: South Bay Radiology Spanish Surname	477	93 (19%)	81
Facility 2: UCSD Center for Women's Health	886	549 (62%)	525
Facility 3: Lybrand Mammography & Education Center	373	200 (54%)	187
Facility 4: Alvarado Breast Center	685	519 (76%)	485
Facility 5: Mercy Hospital	25	9 (36%)	7
Facility 6: Tri-City Medical Center	856	426 (50%)	424
All Facilities	3701	1971 (53%)	1,863

### Subject Attrition

Subject attrition rates varied among the six facilities: 22% of subjects recruited at UCSD Center for Women's Health were subsequently excluded, 19% at South Bay Radiology, 14% at the Alvarado Breast Center, 14% at Mercy Hospital, 12% at the Tri-City Outpatient Imaging Center, and 9% at the Lybrand Mammography and Education Center. Reasons for subject attrition are presented below in Table 3.

Table 3  
Reasons for Subject Attrition

Reason	Percent of all subjects excluded from the study
Concurrently Enrolled in the Women's Health Initiative	39%
Returned to Facility Prior to Targeted Appointment Month	31%
Physician-Related Issues (e.g., physician retired)	17%
Refused Telephone Interview	6%
Wrong Age	3%
Other / Miscellaneous	2%
Deceased	2%

### Survey Data

Overall, 1,818 telephone interviews were completed; interviewing concluded in September, 1997. Of the 1,863 subjects recruited, 18 (1%) refused the survey and were excluded from the study. Interviewers were unable to reach 27 women (1%); these subjects remain in the study.

Using survey data, potential correlates to annual mammography were explored. These data were presented at scientific conferences and the abstracts are attached (Appendix D). Presentations focused on: a) correlates of repeat screening in Latinas and Anglos, b) rates and correlates of discomfort, and c) age-specific correlates of annual mammography. In addition, one of the graduate assistants working on the project focused on rates and correlates of discomfort associated with mammography for her Master's thesis and subsequently a manuscript was completed. The manuscript has been accepted for publication in Radiology and is currently in press (Appendix E).

## Outcome Data

The intervention for the first wave of subjects was implemented in June, 1996. Primary outcome data collection was completed in June, 1998. Five hundred and twenty three subjects were randomly assigned to the control group, 519 to the standard facility reminder group, and 520 to the physician-endorsed reminder group. Secondary outcome data collection (i.e., return for mammography within 6 months of the first day of the targeted appointment month) was completed in November, 1998. A manuscript regarding the study results presented below is currently under review (Appendix F).

Table 4 on the following page examines the comparability among the intervention groups on seven characteristics: type of insurance, family history of breast cancer, education, ethnicity, marital status, family income and age. The groups did not differ on any of these factors suggesting that randomization was successful.

Table 4  
Comparisons of Groups on Selected Characteristics

	Physician- Endorsed % (n)	Standard Facility % (n)	Control % (n)	p-value
Type of Insurance				0.95
None	4.7 (24)	4.6 (23)	4.7 (24)	
Medicare only	1.4 (7)	1.8 (9)	2.1 (11)	
No Medicare but other	66.2 (339)	64.6 (326)	66.9 (345)	
Medicare and other	27.7 (142)	29.0 (146)	26.4 (136)	
Family History of Breast Cancer	31.1 (156)	25.4 (123)	30.7 (154)	0.09
Education				0.20
< 8th grade	2.5 (13)	4.0 (20)	2.9 (15)	
8-11th grade	3.9 (20)	2.8 (14)	4.9 (25)	
High school graduate	20.5 (105)	22.8 (115)	23.7 (122)	
Post high school, trade school	2.5 (13)	3.4 (17)	4.1 (21)	
1-3 years of college	36.7 (188)	33.9 (171)	31.5 (162)	
College graduate	14.7 (75)	17.1 (86)	18.6 (96)	
Some graduate work	19.1 (98)	16.1 (81)	14.4 (74)	
Ethnicity				0.25
Non-Latina white	87.0 (443)	83.8 (423)	83.5 (430)	
Latina	6.5 (33)	9.3 (47)	7.2 (37)	
African American	2.2 (11)	3.2 (16)	4.3 (22)	
Other	4.3 (22)	3.8 (19)	5.1 (26)	
Marital Status				0.54
Married / living as married	64.1 (325)	64.8 (326)	61.7 (316)	
Widowed	12.6 (64)	11.9 (60)	14.8 (76)	
Divorced / separated	20.3 (103)	20.1 (101)	18.4 (94)	
Never married	3.0 (15)	3.2 (16)	5.1 (26)	
Family Income				0.18
< \$20,000	20.8 (93)	15.1 (67)	18.3 (80)	
\$20,001 - 40,000	35.1 (157)	40.2 (178)	39.8 (174)	
≥ \$40,001	44.1 (197)	44.7 (198)	41.9 (183)	
Age: mean (sd)	60.0 (7.3)	60.5 (7.5)	60.2 (7.5)	0.60

The following tables describe the main results of the preliminary analysis comparing the three intervention groups with respect to the primary outcome: returning within the 8-week monitoring period. Table 5 displays return rates by group. The overall difference among the return rates was highly significant ( $p < 0.001$ ). Table 6 presents the Bonferroni pairwise comparisons among the groups. There was no difference between the physician-endorsed and standard facility groups. However, both of these groups had significantly higher return rates than the control group.

Table 5  
Comparisons of Return Rates

Group	Return Rate	Group Size
Physician-Endorsed	47.7% (248)	520
Standard Facility	46.6% (242)	519
Control	28.3% (148)	523

$\chi^2 = 51.3$  (2 df),  $p$ -value  $< 0.001$

Table 6  
Multiple Comparisons with Bonferroni Adjustment\*

Comparison	Chi-Square	p-value
Physician-endorsed vs. Standard facility	0.12	0.73
Physician-endorsed vs. Control	41.6	$< 0.001^{**}$
Standard facility vs. Control	37.4	$< 0.001^{**}$

\* Each comparison tested at  $0.05/3 = 0.017$  level of significance

\*\* Significant at 0.017 level of significance

Table 7 on the following page examines group differences using logistic regression with and without adjusting for other factors. As shown, the odds ratios changed very little after adjustment. The odds of returning within the 60 day window in either the physician (2.19) or facility letter (2.06) groups were slightly over two times that of the control group after adjustment.

Table 7  
Logistic Regression Analyses Comparing Groups on the Probability of Returning Within 8 Weeks  
Unadjusted and Adjusted for Selected Characteristics

	OR	95% Confidence Interval	p-value
<u>Unadjusted</u>			
Control	1.0		
Physician	2.31	1.79 - 2.99	<0.001
Facility	2.21	1.71 - 2.86	<0.001
<u>Adjusted*</u>			
Control	1.0		
Physician	2.19	1.64 - 2.93	<0.001
Facility	2.06	1.54 - 2.76	<0.001

\* Adjusted for age, ethnicity, family history of breast cancer, educational status, marital status, and family income.

We also examined whether the differences in return rates among intervention groups varied by facility by fitting a model that included the main effects for group and facility and the group by facility interaction (excluding the facility that contributed 6 subjects). The interaction term was not statistically significant ( $p=0.45$ ), indicating that the differences among the study groups did not depend on facility. Dropping the interaction term, the main effects model with intervention group and facility did not indicate a significant facility effect ( $p=0.11$ ), suggesting that return rates did not vary significantly among the facilities.

As noted earlier, following the 60-day follow-up interval, subjects in the control group received a reminder. However, return rate data continued to be collected for an additional 4 months. At 6-months post-intervention, return rates for the remaining evaluable conditions, the physician letter and facility letter groups, were 346/520 (66.5%) and 347/519 (66.9%), respectively, and did not differ from each other,  $\chi^2(1) = .01$ ,  $p=.91$ .

#### Participating Physician Questionnaire

Upon completion of the intervention, a 13 item questionnaire was mailed to 67 of the participating physicians regarding the intervention and the study in general. We were unable to approach 15 of the 82 physicians recruited due to relocation or retirement. Multiple attempts were made to reach physicians (i.e., re-mailing the questionnaire, mailing a shortened version of the questionnaire with 4 items, making reminder calls). Forty-three full and 2 post card questionnaires were completed by physicians (67%). In general, participating physicians were satisfied with the physician endorsement reminder system (PER); 73% of respondents reported that they were "somewhat" or "very satisfied." The majority (71%) of physicians stated that it was "somewhat" or "very likely" that they would continue to participate in the PER reminder system program. The questionnaire is attached (Appendix G) and results are presented on the following page.

Table 8  
Physician Questionnaire Results

	N=45
<hr/>	
General Level of Satisfaction with the Physician-Endorsed Reminder Letter (PER):	
Very satisfied	49%
Somewhat satisfied	24%
Neutral	16%
Somewhat dissatisfied	2%
Very dissatisfied	9%
Percent Whose Patients Commented on the PERs (to the Physician or his/her Staff)	54%
Percent who Endorsed the Following Potential Advantages of the PER:	
Encourages patients to schedule an annual exam	80%
Encourages patients to return to the mammography facility	42%
Saves time for physician and his/her staff	42%
Patients like it	36%
Helps my relationships with patients	29%
Helps my relationship with the mammography facility	13%
Percent who Endorsed the Following Potential Disadvantages of the PER:	
Did not like providing my letterhead	5%
Would rather send own reminder	5%
Patients do not like the PER	0%
Likelihood that Physician will Continue to Participate in this Reminder System Program (if offered):	
Very likely	46%
Somewhat likely	25%
A 50/50 chance	7%
Somewhat unlikely	5%
Very unlikely	18%

### Mammography Facility Interviews

We interviewed mammography facility personnel after primary outcome data collection was completed to assess their perceptions of the intervention and the study procedures in general. At five of the facilities in-person meetings were held; one facility preferred to fill out a questionnaire. Overall, facility personnel had positive comments about the study but shared concerns regarding the time and resources needed to institutionalize the PER reminder system. Questions for mammography facility staff are attached (Appendix H) and results are summarized on the following page.

Table 9  
Mammography Facility Interview Results

	N=6
Mean Number of Hours Currently Spending Generating Reminder Letters per Month	2.2
Mean Number of Hours Willing to Spend Generating Reminder Letters per Month	3.3
Percent of Participating Facilities who have Software Capable of Generating Reminder Letters	83%
Likelihood that the Facility Would Generate PERs if Found to be Significantly More Effective than Standard Facility Reminder Letters:	
Very likely	0%
Somewhat likely	17%
A 50/50 chance	33%
Somewhat unlikely	0%
Very unlikely	50%
Reasons Facility Would not be Likely to Send out PERs:	
Current system in place is effective	
Would need to do a cost-benefit analysis comparing PERs to facility reminders	
Patients do not like change	
Too much organization is necessary	
Will create more work	
Have more control sending reminders on our letterhead	
Too time consuming	
Some women have more than 1 physician	
Overall Impressions of the Study:	
Study had very little impact on our staff	
Project staff was excellent	
Patients felt special/honored to participate	
It was easy to participate; did not impact our ability to deliver care	
Project staff was professional, polite	
Project staff was very organized, did the work for us	



## 7. KEY RESEARCH ACCOMPLISHMENTS

- Recruited 6 mammography facilities (i.e., study sites)
- Recruited 82 referring physicians
- Recruited 1,863 study subjects (were able to collect outcome data for 1,562 of the 1,863)
- Developed “physician-endorsed” and “standard mammography facility” reminder letters
- Developed a 43 item telephone interview
- Conducted the telephone interview with 1,818 study subjects
- Randomly assigned subjects to group and implemented the intervention
- Examined potential correlates of annual mammography screening
- Analyzed outcome data
- Presented research findings via 5 poster sessions at scientific conferences and 2 manuscripts (one currently under review, one in press)
- Wrote a chapter of a text book regarding behavioral medicine and women summarizing mammography screening adherence issues (Appendix I)
- Developed and conducted surveys with participating physicians and facilities regarding their participation in the study

## 8. REPORTABLE OUTCOMES / BIBLIOGRAPHY

### Manuscripts

Dullum, J.R., Lewis, Elizabeth, E.C., & Mayer, J.A. Rates and correlates of discomfort associated with mammography. Radiology. In press.

Mayer, J.A., Lewis, E.C., Slymen, D.J., Dullum, J., Kurata, H., Holbrook, A., Elder, J.P., & Williams, S.J. Patient reminder letters to promote annual mammograms: a randomized controlled trial. Under review.

### Book Chapter

Mayer, J.A. Breast cancer screening: improving adherence. (1998). In Behavioral medicine and women: a comprehensive handbook. Blechman, E.A., & Brownell, K.D., eds. New York: Guilford Publications, Inc.

### Abstracts

Lewis, E.C., Dullum, J.I., Holbrook, A.C., & Mayer, J.A. (1996, March). Correlates of repeat annual mammograms in Latinas and Anglos. Paper presented at the Fourth International Congress of Behavioral Medicine, Washington, D.C.

Dullum, J.I., Holbrook, A.C., Lewis, E.C., & Mayer, J.A. (1996, March). Rates and correlates of discomfort associated with mammography. Paper presented at the Fourth International Congress of Behavioral Medicine, Washington, D.C.

Holbrook, A.C., Dullum, J.I., Lewis, E.C., & Mayer, J.A. (1996, March). Age-specific correlates of annual screening mammography. Paper presented at the Fourth International Congress of Behavioral Medicine, Washington, D.C.

Mayer, J.A., & Lewis, E.C. (1997, October - November). A trial comparing the effects of two types of mammography reminder letters: recruitment issues. Paper presented at the Department of Defense Breast Cancer Research Program Meeting, Washington, D.C.

Lewis, E.C., Mayer, J.A., Slymen, D., Dullum, J.R., Kurata, H., Holbrook, A., Elder, J., Williams, S. (1999). Promoting annual mammography with a physician-endorsed reminder letter. Paper presented at the 20<sup>th</sup> annual meeting of the Society of Behavioral Medicine, San Diego, California.

### Degrees Obtained Supported by This Award

Joanna Dullum. (1996). Masters thesis entitled, "Rates and Correlates of Discomfort Associated with Mammography." Graduate School of Public Health, San Diego State University.

## 9. CONCLUSIONS

The results of this randomized controlled trial indicated that reminders mailed to patients from either their physician or their mammography facility doubled the likelihood that patients would receive a mammogram within 13 months of their previous mammogram relative to patients who received no reminder. The two types of reminders showed no differential effects on outcome at both the 2 and 6 month followups. The pattern of findings persisted after controlling for potential confounders, and was seen within each participating facility.

A previous study that used a randomized 4-group design in a health maintenance organization (HMO) setting compared the effects on mammography compliance of a recommendation letter from each subject's primary care physician with a recommendation letter from the medical director of the HMO's breast cancer screening program (14). The compliance rates for these groups were 46% and 47%, respectively (n.s.). The authors questioned whether the lack of effect of the personal physician letters would generalize to fee-for-service practice settings. Our results replicated those of the HMO study both with respect to the actual compliance rates and the lack of differential effects. Women may perceive their primary care physicians, mammography facilities, and HMO-affiliated screening programs as equally credible sources for mammography recommendations (for both initial and repeat mammograms) if they are familiar with the source. To our knowledge, no other mammography compliance studies have compared letters from primary care physicians with letters from a program director or mammography facility director.

A unique feature of our intervention was that it targeted an initially adherent patient's next (i.e., annual) mammogram. Because the previous rate of regular mammography in our sample was found in the baseline survey to be high, we questioned whether this apparently motivated group would benefit from any type of reminder. Yet, over the 60-day follow-up interval, subjects who had received a letter had twice the likelihood of getting a mammogram. Our findings that reminder letters significantly increased mammography compliance relative to no letters were consistent with the findings of a recently published meta-analysis. The author found that of the 11 U.S. studies that compared the effects of mailed patient reminders to no reminders on mammography use, women who received reminders were approximately 50% more likely to get a mammogram (15).

Several methodological issues related to this study should be addressed. First, because research staff (rather than staff at physician offices and mammography facilities) mailed the reminder letters, the results of this trial should be interpreted as an indication of the interventions' efficacy (versus effectiveness). Although we do not have data on actual receipt of the letters by the subjects, all subjects in Groups 1 and 2 were mailed letters at the appropriate time. Mailing procedures at physicians' offices and mammography facilities likely show greater variability. Second, some may argue that the

60-day follow-up interval for the study as a whole (all 3 groups) may be too brief. A longer interval would have raised ethical issues specific to withholding "usual care" reminders to women in the delayed treatment control group, given the guidelines of annual mammograms endorsed by many medical/health organizations. Our main results, therefore, must be viewed as relatively "short-term" outcomes. However, from a mammography facility's perspective, the tendency that was found for these letters to have an immediate impact is beneficial with respect to anticipated patient flow and staffing. Also, from the patient's perspective, planning appointments at precise intervals, in conjunction with a birthday, anniversary, etc., may help her remember when she is due for her screening and could work synergistically with a mailed reminder system. There is some evidence that of screened women who obtain a subsequent screening mammogram, the majority do so within 12 to 14 (16) or 12 to 13 (17) months after the previous mammogram. The benefits of conducting screening in women 50 and older at precise 12-month intervals may be less clear from a disease detection perspective (18). In contrast, for women age 40 – 49 (who since 1997 have been included in the screening recommendations of the National Cancer Institute (19)), there is some evidence that screening every year (vs. longer intervals) may increase the sensitivity of mammography, possibly due to rapid tumor growth (20). Therefore, interventions that promote adherence to fairly precise intervals may be particularly relevant for this younger age group.

Third, self-selection biases may limit the external validity of these findings. The participating fee-for-service facilities, physicians, and patients may not be representative of the available sampling populations of these entities (approximately one-half of the physicians and patients that were approached entered the study). However, the impact of this potential bias on baseline rates of mammography or response to the intervention is unknown. Our results also may only generalize to fee-for-service mammography facilities and patients who are white or Latina. Nevertheless, as noted earlier, our results were consistent with those of Taplin et al.'s (14) HMO-based trial.

As noted above, ours is one of the few studies to have focused on repeat mammograms. More specifically, we selected subjects based on them obtaining a mammogram (at study entry) and followed them prospectively. Furthermore, the content of the intervention letters, as well as the cutoffs used to define adherence, was tailored for an interval adherence trial. Additional strengths included 1) the inclusion of multiple facilities, a fairly large sample of physicians and a large sample of patients; 2) successful randomization of subjects from within referring physicians; 3) the testing of interventions that have a high potential for institutionalization; 4) an 11 to 12 month interval between the interview and receipt of the intervention letters, in order to minimize potential reactivity of the interview procedure; and 5) use of an objective measurement strategy for assessing both the study entry mammogram and the outcome mammogram.

Our findings have straightforward implications for clinical practice. Primary care physicians who do not use patient reminders for promoting regular mammography should consider doing so or refer patients to mammography facilities that use patient reminder systems. Mammography facilities that use reminders that are comparable to those used

for Group 2 subjects should continue to implement them, given their level of effectiveness found in this study across several facilities.

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## APPENDIX A

### Standard Mammography Facility Reminder Letter





Scripps Memorial Hospitals

The Lybrand Mammography  
and Education Center

9888 Genesee Avenue  
Post Office Box 28  
La Jolla, California 92038-0028

(619) 526-6224  
(619) 526-6261 FAX

September 30, 1997

Recommended month for next mammogram: October, 1997

Dear Ms. :

Your last mammogram at The Lybrand Mammography and Education Center was approximately one year ago. For women in your age category, the American Cancer Society recommends routine screening mammography each year, along with yearly clinical breast exam and monthly breast self-examination. Currently, you are due for your annual mammogram.

Please call your personal physician at your earliest convenience to obtain a referral for your next mammogram. You also should make an appointment with him/her for your annual clinical breast exam.

We look forward to seeing you.

Sincerely,

The Lybrand Mammography and Education Center  
(619) 626-6224

## APPENDIX B

### Physician Endorsement Reminder Letter

ROBERT P. BROUILLARD, M.D., F.A.C.P.

Internal Medicine  
Hematology and Oncology

9850 Genesee Avenue, Suite 830  
La Jolla, CA 92037  
Telephone (619) 552-1410

September 30, 1997

Recommended month for next mammogram: October, 1997

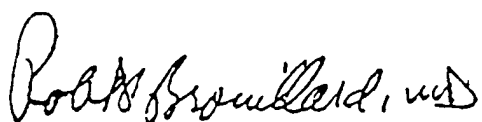
Dear Ms. :

Your last mammogram at The Lybrand Mammography and Education Center was approximately one year ago. For women in your age category, the American Cancer Society recommends routine screening mammography each year, along with yearly clinical breast exam and monthly breast self-examination. Currently, you are due for your annual mammogram.

Please call me at 552-1410 at your earliest convenience to schedule an appointment for your annual clinical breast exam and to receive your mammography referral. Once you obtain your referral, call The Lybrand Mammography and Education Center at 626-6224 to make an appointment for your annual mammogram.

I look forward to seeing you.

Sincerely,



Robert P. Brouillard, M.D., F.A.C.P.

APPENDIX C

Telephone Survey

## PICTURE OF HEALTH MAMMOGRAPHY PROJECT TELEPHONE INTERVIEW

Hello, my name is \_\_\_\_\_, with the Picture of Health Mammography Project. May I speak with \_\_\_\_\_? Hello \_\_\_\_\_, this is \_\_\_\_\_ of the Picture of Health Project. When you had your last appointment at \_\_\_\_\_ you signed a letter of consent to participate in our study; one part of the study is this telephone interview. At this time we would like to ask you some questions regarding mammography and breast cancer, in general. I expect this telephone interview to take about 15 - 20 minutes. Is this a good time for you to answer these questions?

*(If not, ask if there is a better time to call. Thank the subject for her time and let her know we will call her back at the convenient time she specified).*

Before I begin to ask you the questions, I would like to confirm that you have never had breast cancer -- for this study we are focusing only on women who have never had breast cancer. Have you had breast cancer?

*(If yes, thank woman for her time, politely end interview)*

O.K.. then let's get started. As you answer, remember that we just want you to answer openly; there are no right or wrong answers.

### **Provider Variables** - DO NOT READ QUESTION HEADINGS

1. **Is there a particular doctor's office, clinic, health center or other place that you usually go to if you are sick or need advice about your health?**

1=yes

2=no (GO TO QUESTION #3)

8=don't know (GO TO QUESTION #3)

2. **What kind of place is it - a doctor's office, a hospital, a clinic, a health center or some other place? (CHECK ONLY ONE)**

01=doctor's office (private office or group practice)

02=hospital emergency room

03=hospital outpatient clinic

04=health center

private health clinic

private neighborhood health clinic

05=public health clinic

06=HMO/prepaid group practice, "group health"

07=Kaiser facility

08=Cigna health plan facility

09=PPO; preferred provider organization

10=medical facility (type not listed above)

3. **Our records show that Dr. \_\_\_\_\_ referred you for your most recent mammogram. Is he/she your regular doctor?**

1=yes

2=no

4. **What type of doctor is he/she?**

1=family or general practice

2=internist

3=gynecologist

4=other

8=don't know

5. **Are you presently covered by any of the following kinds of health insurance? ARE YOU COVERED BY...?**

(READ LIST AND RECORD A RESPONSE FOR EACH ITEM):

**A. Commercial insurance, like Blue Cross, Prudential, or Medigap?**

1=yes

2=no

8=don't know

**B. A Health Maintenance Organization (HMO) or Individual Practice Association (IPA) like Kaiser or Maxicare?**

1=yes

2=no

8=don't know

**C. Preferred Provider Option?**

1=yes

2=no

8=don't know

**D. Medicare?**

1=yes

2=no

8=don't know

**E. Medical?**

1=yes

2=no

8=don't know

**F. Secure Horizons?**

1=yes

2=no

8=don't know

**G. Any other health insurance?**

1=yes, specify: \_\_\_\_\_

2=no

8=don't know

**Health History**

6. **Has a doctor ever told you that you had a lump or tumor in your breast or breasts?**

1=yes

2=no

7. **Have you ever had a biopsy of your breast, in which a small segment of tissue was removed or a needle was used to extract fluid?**

1=yes

2=no (GO TO QUESTION #9)

8=don't know (GO TO QUESTION # 9)

8. **Did you have a surgical biopsy where a small segment of tissue was removed or was a needle used to extract fluid?**

1=surgical biopsy

2=needle aspiration biopsy

8=don't know

9. Is there a history of breast cancer in any one of the following members of your family? Remember we are talking only about breast cancer. (READ):

**A. your mother?**

1=yes

2=no

8=don't know

**B. any sister?**

1=yes

2=no

8=don't know

**C. any grandmother?**

1=yes

2=no

8=don't know

**D. any aunt?**

1=yes

2=no

8=don't know

**E. any daughter?**

1=yes

2=no

8=don't know OR

**F. any granddaughter?**

1=yes

2=no

8=don't know

10. Have you ever been told by a doctor that you have fibrocystic breasts, a condition that is not cancer but that makes your breasts feel lumpy or sore most of the time?

1=yes

2=no

8=don't know

**Breast Cancer Screening History**

11. Prior to your recent mammogram, had you ever had a mammogram before?

1=yes

2=no (GO TO QUESTION #17)



12. Including the last one, how many mammograms have you ever had? \_\_\_\_\_  
(IF WOMAN CANNOT GIVE AN EXACT NUMBER, ASK FOR AN ESTIMATE)
13. Prior to the mammogram you had in the past few weeks, when was the mammogram you had before that?
- 1=less than 1 year
  - 2=over 1 year ago
  - 3=over 2 years ago
  - 4=over 3 years ago
  - 5=over 4 years ago
  - 6=over 5 years ago
  - 7=6 - 10 years ago
  - 8=more than 10 years ago
  - 9=don't know
14. Why did you have that mammogram...because you had a breast problem or for a routine check-up, that is, you did not have any symptoms (problems)?
- 1=had a breast problem
  - 2=routine check-up
15. Have you ever had a mammogram where the results were NOT normal or the results were inconclusive?
- 1=yes
  - 2=no (GO TO QUESTION #17)
  - 8=don't know (GO TO QUESTION #17)
16. What happened as a result of the mammogram with abnormal or inconclusive results?
- 1=had a second mammogram
  - 2=had a biopsy (negative)
  - 3=other/specify: \_\_\_\_\_
- 
17. How would you describe your pattern of having routine mammograms?  
(READ LIST):
- 1=have had only one or have them sporadically (GO TO QUESTION #18)
  - 2=have had them every 2-3 years on a regular basis (GO TO QUESTION #18), OR
  - 3=have them annually (GO TO QUESTION #19) ?

18. I'm going to mention several reasons that may explain why you do not have annual mammograms. Please tell me how much each reason applies to you. Your options are: applies to you a great deal, applies somewhat, or does not apply at all. The first reason is... (READ OPTIONS):

**A. "my doctor doesn't recommend it annually"**

1=applies a great deal

2=applies somewhat, OR

3=does not apply at all ?

**B. "someone other than my doctor recommended against annual mammograms"**

1=applies a great deal

2=applies somewhat, OR

3=does not apply at all ?

**C. "I'm concerned about radiation"**

1=applies a great deal

2=applies somewhat, OR

3=does not apply at all ?

**D. "the exam is painful"**

1=applies a great deal

2=applies somewhat, OR

3=does not apply at all ?

**E. "there are financial reasons, cost, my insurance does not cover it at all or not annually"**

1=applies a great deal

2=applies somewhat, OR

3=does not apply at all ?

**F. "it's not necessary, I have no problems, all previous exams have been fine"**

1=applies a great deal

2=applies somewhat, OR

3=does not apply at all ?

**G. "I don't think about it"**

1=applies a great deal

2=applies somewhat, OR

3=does not apply at all ?

**H. "I'm too busy"**

1=applies a great deal

2=applies somewhat, OR

3=does not apply at all ?

**I. "I have no family history of breast cancer"**

1=applies a great deal

2=applies somewhat, OR

3=does not apply at all ?

**J. "I procrastinate"**

1=applies a great deal

2=applies somewhat, OR

3=does not apply at all ?

**K. "I do not think it is important"**

1=applies a great deal

2=applies somewhat, OR

3=does not apply at all ?

**L. "thinking about mammography makes me anxious"**

1=applies a great deal

2=applies somewhat, OR

3=does not apply at all ?

**M. "I fear that they'll find something"**

1=applies a great deal

2=applies somewhat, OR

3=does not apply at all ?

**N. "I'm embarrassed"**

1=applies a great deal

2=applies somewhat, OR

3=does not apply at all ?

**O. "I don't have transportation"**

1=applies a great deal

2=applies somewhat, OR

3=does not apply at all ?

**P. "I'm in poor health"**

1=applies a great deal

2=applies somewhat, OR

3=does not apply at all ?

**Q. Are there any other reasons? (SPECIFY):** \_\_\_\_\_

19. I'm going to mention several reasons that may explain why you have annual mammograms. Please tell me how much each reason applies to you. Your options are: applies to you a great deal, applies somewhat, or does not apply at all. The first response is... (READ OPTIONS):

**A. "my doctor recommends it"**

1=applies a great deal

2=applies somewhat, OR

3=does not apply at all ?

**B. "organizations such as the American Cancer Society recommend it"**

1=applies a great deal

2=applies somewhat, OR

3=does not apply at all ?

**C. "my friends, family, others recommend it"**

1=applies a great deal

2=applies somewhat, OR

3=does not apply at all ?

**D. "it is effective in detecting cancer early"**

1=applies a great deal

2=applies somewhat, OR

3=does not apply at all ?

**E. "I want peace of mind"**

1=applies a great deal

2=applies somewhat, OR

3=does not apply at all ?

**F. "it is convenient"**

1=applies a great deal

2=applies somewhat, OR

3=does not apply at all ?

**G. "I have a family history of breast cancer"**

1=applies a great deal

2=applies somewhat, OR

3=does not apply at all ?

**H. "I'm afraid I'll develop breast cancer"**

1=applies a great deal

2=applies somewhat, OR

3=does not apply at all ?

**I. "I have a history of benign breast problems (cysts, etc.)"**

1=applies a great deal

2=applies somewhat, OR

3=does not apply at all ?

**J. "it's the sensible thing to do"**

1=applies a great deal

2=applies somewhat, OR

3=does not apply at all ?

**K. Are there any other reasons? (SPECIFY): \_\_\_\_\_**

20. I want you to think about the mammogram you had most recently. When the mammography equipment was pressing against your breasts during the X-ray, how did you feel? (READ):

1=no physical discomfort

2=slight physical discomfort

3=moderate physical discomfort

4=substantial physical discomfort OR

5=extreme physical discomfort ?

21. A physical breast examination is when the breast is felt for lumps by a doctor or other health professional. Have you ever had a physical breast examination?

1=yes

2=no (GO TO QUESTION #24)

8=don't know (GO TO QUESTION #24)

22. When did you have your last physical breast examination?

1=less than 1 year

2=over 1 year ago

3=over 2 years ago

4=over 3 years ago

5=over 4 years ago

6=over 5 years ago

7=6 - 10 years ago

8=more than 10 years ago

9=don't know

23. Why did you have your last physical breast exam...Because you had a breast problem or for a routine check-up, that is you did not have any symptoms (problems)?

1=had a breast problem

2=routine check-up

24. Do you examine your own breasts for lumps or other changes?

1=yes

2=no (GO TO QUESTION #26)

8=don't know (GO TO QUESTION #26)

25. How often do you examine your breasts?

\_\_\_\_\_ times per

\_\_\_\_\_

day

\_\_\_\_\_

week

\_\_\_\_\_

month

\_\_\_\_\_

year

\_\_\_\_\_

other/specify: \_\_\_\_\_

88=don't know

**Knowledge/Beliefs**

26. How often is routine mammography recommended for women in your age range (50 and older) by experts such as the American Cancer Society?

1=never  
2=every 2 -5 years  
3=annually  
4=once  
5=only when there's a problem  
6=other/specify: \_\_\_\_\_  
8=don't know

27. What proportion of women do you think will get breast cancer at some time during their lives? Do you think it is...(READ CHOICES):

1=1 in 4  
2=1 in 8  
3=1 in 25, OR  
4=1 in 50 ?  
8=don't know (DO NOT READ THIS ALTERNATIVE)

28. What are your chances of getting breast cancer sometime during your lifetime? Do you think it is...(READ CHOICES):

1=1 in 4  
2=1 in 8  
3=1 in 25, OR  
4=1 in 50 ?  
8=don't know (DO NOT READ THIS ALTERNATIVE)

29. Are women 50 years and older more likely, less likely, or equally likely to get breast cancer than women younger than 50?

1=more likely  
2=less likely  
3=equally likely  
4=other/specify: \_\_\_\_\_  
8=don't know

### Intentions

30. What is the likelihood that you will have another routine screening mammogram next year, even if your doctor does not suggest one? Is it...(READ):

1=very unlikely  
2=somewhat unlikely  
3=a 50/50 chance  
4=somewhat likely, OR  
5=very likely ?

31. If your doctor recommends one, what is the likelihood that you will have another routine screening mammogram next year? Is it...(READ):

1=very unlikely  
2=somewhat unlikely  
3=a 50/50 chance  
4=somewhat likely, OR  
5=very likely ?

### Efficacy and Outcome Expectations

32. How confident are you that you will be able to schedule a mammogram appointment in the next 12 months (i.e., phone for an appointment, schedule it at a convenient time, etc.)? Are you...(READ):

1=not at all confident  
2=slightly confident  
3=somewhat confident  
4=fairly confident, OR  
5=very confident ?

33. How confident are you that you will be able to complete the appointment once it is scheduled (i.e., drive yourself or obtain transportation, get the money and/or insurance to pay for the mammogram, etc.)? Are you...(READ):

1=not at all confident  
2=slightly confident  
3=somewhat confident  
4=fairly confident, OR  
5=very confident ?

34. **How confident are you that having annual mammograms will improve your chances of survival if you have breast cancer? Are you...(READ):**

1=not at all confident  
2=slightly confident  
3=somewhat confident  
4=fairly confident , OR  
5=very confident ?

**Recent Mammography Experience**

**For the next 3 questions, I want you to think again about your most recent mammogram experience. Please answer these questions openly; your answers will not be shared with mammography facility staff. I will read a statement, and I'd like you to tell me how much you agree or disagree with it...(READ):**

35. **"I was very satisfied with the care I received."  
Do you (READ):**

1=strongly disagree  
2=disagree  
3=neutral  
4=agree, OR  
5=strongly agree ?

36. **"I feel confident that the mammogram was taken properly."  
Do you (READ):**

1=strongly disagree  
2=disagree  
3=neutral  
4=agree, OR  
5=strongly agree ?

37. **"The person was too rough when taking the mammogram."  
Do you (READ):**

1=strongly disagree  
2=disagree  
3=neutral  
4=agree, OR  
5=strongly agree ?



**Demographic Information**

**38. In what month and year were you born?**

(date: month \_\_ , year \_\_ )

**39. What was the highest level of education that you completed?**

1=less than eighth grade

2=8th grade to 11th grade

3=high school graduate

4=post high school, trade or technical school

5=1 -3 years of college

6=college graduate

7=some graduate work or graduate degree

**40. Which of the following best describes your ethnic or racial group? (READ):**

1=white, or Caucasian, not of Hispanic origin

2=Mexican American, Mexican/Mexicano, Hispanic, Puerto Rican, Cuban, Chicano,  
other Latin American, or other Spanish

3=African American

4=American Indian

5=Asian

6=Pacific Islander

7=other/specify: \_\_\_\_\_

**41. What is your present marital status?**

1=married or living as married

2=widowed

3=divorced

4=separated

5=never married

**42. What is your current employment status?**

1=working at a full-time job

2=working at a part-time job

3=not working, but looking for work

4=a full-time homemaker

5=a non-salaried volunteer

6=retired

7=unable to work due to disability

8=other/specify: \_\_\_\_\_

43. Please stop me when I get to the category that best describes your family's total annual income. Is it... (READ):

1=less than \$10,000

2=10,001 to 15,000

3=15,001 to 20,000

4=20,001 to 25,000

5=25,001 to 30,000

6=30,001 to 40,000

7=40,001 to 50,000

8=50,001 and over

9=don't know (DO NOT READ THIS OPTION)

10=refused (DO NOT READ THIS OPTION)

**WE ARE NOW FINISHED WITH THE TELEPHONE INTERVIEW. ON BEHALF OF THE PICTURE OF HEALTH STAFF, I'D LIKE TO THANK YOU FOR YOUR TIME AND INTEREST IN THE STUDY. YOUR INPUT IS VERY VALUABLE TO US.**

**HAVE A GOOD DAY/EVENING...**

## APPENDIX D

### Abstracts (5)

### CORRELATES OF REPEAT ANNUAL MAMMOGRAMS IN LATINAS AND ANGLOS

Elizabeth C. Lewis, M.P.H., Joanna I. Dillum, B.S., Angela C.  
Holbrook, B.S., and Joni A. Mayer, Ph.D., San Diego State University

Although the number of women reporting that they have ever had a mammogram has risen in recent years, annual screening rates remain low. To date, barriers and facilitators to repeat annual mammography for various ethnic groups have not been thoroughly explored. We are in the process of conducting a 43 question telephone interview with 1800 women recruited from 4 San Diego County mammography facilities. To date, 102 women with a mean age of 61 years have been interviewed. Sixty-eight percent of respondents self-identified as Caucasian, 26 % as Latinas, 2% as African American, 1% Asian, and 4% as "other".

Results from our preliminary analysis suggest differences between Latinas and Anglos in factors related to repeat screening. Intentions to have a mammogram next year, which has been found to predict actual adherence, was of main interest in the analysis. Overall, the proportions of respondents reporting it was "very likely" they would have a mammogram was 77% for Anglos and only 31% for Latinas; mean levels of intentions between groups were statistically different ( $p < .01$ ). Barriers unique to Latinas, that were significantly related to intentions to have a mammogram included: being too busy and being in poor health, while barriers unique to Anglos were: not thinking about it, not necessary, all previous exams were fine, unimportance of mammography, and fear of finding something. Anticipated sample size at the time of presentation is 700 and discussion will focus on the need to develop adherence interventions appropriately - considering similarities and differences in correlates related to annual mammography between ethnic groups, when working with diverse populations.

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### RATES AND CORRELATES OF DISCOMFORT ASSOCIATED WITH MAMMOGRAPHY

Joanna I. Dullum, B.S., Angela C. Holbrook, B.S., Elizabeth C. Lewis,  
M.P.H., and Joni A. Mayer, Ph.D., San Diego State University

Annual screening mammograms are recommended for women over 50 for the early detection of breast cancer. Even though the benefits of early detection have been demonstrated, women are not following the screening guidelines. Physical discomfort with mammographic compression has been cited as one perceived barrier to obtaining or returning for mammograms, but the studies have yielded conflicting results. This study will: 1) evaluate the frequency with which women ages 50-74 in San Diego report physical discomfort with the procedure and 2) determine whether there is an association between discomfort and intentions to return for a mammogram the following year. Intentions have been shown to be a strong predictor of actual mammography adherence.

Data for this study were cross sectional and were collected via a 43-item telephone interview. Subjects were interviewed within 4 weeks after their recent mammogram. Preliminary data have been collected on 102 subjects with an anticipated sample size of 700. Caucasians represented 68% of the sample, Hispanics 26%, African American 2%, Asian 1% and Other 4%. The preliminary analysis indicated that for the 102 subjects, 10.8% reported no discomfort, 40.2% slight discomfort, 34.3% moderate discomfort, 12.7% substantial discomfort, and 2% extreme discomfort; thus, 49% had  $\geq$  moderate discomfort. An unexpected finding was that discomfort was positively, significantly correlated with intention to have a future mammogram ( $r = .20$ ,  $p < .05$ ); with more discomfort predicting greater intentions. Analysis of the completed data set will reveal whether this finding is stable. Additionally, other correlates of mammography discomfort will be explored.

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AGE-SPECIFIC CORRELATES OF ANNUAL  
SCREENING MAMMOGRAPHY

Angela C. Holbrook, B.S., Joanna I. Dillum, B.S., Elizabeth C. Lewis,  
M.P.H., Joni A. Mayer, Ph.D., San Diego State University

Although the American Cancer Society recommends mammography annually for women 50-74, some women do not comply because of a variety of barriers, some of which may be age-specific. Our study explores differences between women 50-64 and 65-74 years on barriers and facilitators related to annual mammography screening. Our data are based on a 43 question telephone interview of women residing in San Diego County recruited from 4 mammography facilities.

Intentions to have a mammogram next year, which has been found to predict annual adherence, was of main interest in the analysis.

Preliminary analysis of 102 subjects showed that the proportions of younger and older women who said that would "very likely" return in one year following their recent mammogram were 90% and 73%, respectively (n.s.). The facilitator unique to older women that was significantly related to intention to have a mammogram next year was convenience.

Facilitators unique to younger women were: family history of breast cancer, belief that it is the sensible thing to do and primary physician recommends it. Barriers unique to older women were: painful exam, not thinking about it, no family history of breast cancer, fear of finding something and embarrassment. The only significant barrier for younger women was the belief that it is not necessary. Discussion will focus on the need to tailor health promotion interventions to the characteristics of the target population, and will highlight age differences.

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## **A TRIAL COMPARING THE EFFECTS OF TWO TYPES OF MAMMOGRAPHY REMINDER LETTERS. RECRUITMENT ISSUES**

**Dr. Joni A. Mayer and Elizabeth C. Lewis**

Graduate School of Public Health, San Diego State University  
San Diego, CA 92182-4162

Although regular mammography can reduce mortality in women over 50, repeat screening rates remain low. We are conducting a mammography facility-based controlled trial to encourage adherence with annual mammography in women 50-74 years. Specifically, we will test the effectiveness of a "physician-endorsed" mammography appointment reminder letter in comparison with standard facility reminder and control conditions. Additionally, all subjects will be interviewed by phone regarding demographics, knowledge, attitudes, and behaviors related to breast cancer screening. A total of 1,835 women will be recruited from 6 San Diego County mammography facilities at the time of their "study entry mammogram." This presentation will focus on issues related to recruiting subjects, physicians, and facilities.

To date, 1785 subjects have been recruited and data have been collected from 1606. Mean age of subjects is 60 years. Eighty-four percent of subjects self-identified as Caucasian, 8% as Latinas, 4% as African American, 2% as Asian, and 2% as "other." Subjects reported the following annual family incomes: 19% reported income less than \$20,000, 40% reported income of \$20,000 - 40,000, and 42% reported income over \$40,000. The majority (81%) of subjects reported that they have mammograms annually, 12% reported having them every 2-3 years on a regular basis, and 8% reported having had only 1 mammogram, or having them sporadically.

Across the 6 facilities, 53% of eligible women agreed to participate in the study.

**Keywords: Prevention and Health Promotion, Mammography, Recruitment**

This work was supported by the U.S. Army Medical Research and Materiel Command under DAMD-17-94-J-4360.

Subject consent rates and recruitment strategies employed per facility are presented in Table 1. The sixth facility is not included in this table; it provided only 7 subjects. Since the number of women eligible per facility is partially a function of referring physician consent rate, physician consent rates are also presented in Table 1.

	Facility				
	A	B	C	D	E
Subject Consent Rate	30%	78%	63%	53%	51%
Physician Consent Rate	67%	45%	65%	48%	48%
Recruitment Strategies Employed					
Calls Before Appointment	X	X	X	X	X
Packet Mailed Before Appointment (Addresses obtained from facility)			X	X	X
In-person Recruitment		X			
Calls After Appointment	X	X	X	X	X
Packet Mailed After Appointment	X	X	X	X	X

Table 1. Subject and Referring Physician Consent Rates, Recruitment Strategies Employed, by Facility

Results from our preliminary analysis suggest differences between participating and non-participating women for selected variables. Participants were slightly younger than non-participants (60.2 years vs. 61.5 years); mean ages between groups were statistically significant ( $p < .001$ ). Similarly, when women were divided into 2 groups, those 50-64 and those 65-74 years, women in the younger age group were significantly more likely to participate (56%) than women in the older age group (48%),  $\chi^2(1) = 20.8$ ,  $P < .0001$ . At 2 of the 6 facilities there was ethnic/racial diversity among eligible women. Potential subjects from those facilities were divided into 2 groups, those with Spanish surnames and those with non-Spanish surnames. Women with non-Spanish surnames were significantly more likely to participate (49%) than women with Spanish surnames (20%),  $\chi^2(1) = 117.2$ ,  $P < .00001$ .

Facility-based challenges to recruitment include: restrictions on mailed and/or face-to-face recruitment strategies, facility dropping out, low number of eligibles, and facility staff recruitment abilities (e.g., time, interest). Physician-based recruitment challenges were refusal to participate, participates but refers small number of patients, and retirement or relocation. Frequently cited barriers for potential subjects to participate, based on the refusers who were willing to provide this information ( $n = 227$ ), included disinterest and lack of time.



PROMOTING ANNUAL MAMMOGRAPHY  
WITH A PHYSICIAN-ENDORSED  
REMINDER LETTER

Elizabeth C. Lewis, M.P.H., Joni A. Mayer, Ph.D., Don Slymen, Ph.D., Joanna R. Dullum, M.P.H., Heather Kurata, B.A., Angela Holbrook, M.P.H., John Elder, Ph.D., M.P.H., and Steven Williams, Sc.D. Graduate School of Public Health, San Diego State University

Compliance by women 50 years and older to annual mammography guidelines is low. This randomized controlled study assessed the effects of a physician-endorsed reminder letter relative to a mammography facility-endorsed letter or no letter on appointment compliance of women due for annual screening.

Subjects (N=1562) were ages 50 -74 years (mean = 60.2). The ethnic/racial distribution was 84% non-Latina white, 7.6% Latina, 3.2% African American, and 5.2% other. Eleven months following the study entry mammogram (EM) obtained at 1 of 6 participating facilities, Group 1 and Group 2 subjects were mailed reminder letters from their physician or mammography facility, respectively. Group 3 served as a control group. The main outcome measure was the percentage of subjects who had a screening mammogram 12-14 months after the EM as determined by appointment databases. The return rates for Groups 1, 2, and 3 were 47.7%, 46.6% and 28.3% respectively  $\chi^2 = 51.3$ ;  $p < 0.001$ . Bonferroni pairwise comparisons indicated no difference between Groups 1 and 2 but significant differences ( $p < 0.001$ ) between Group 3 and the other two groups. Irrespective of source, reminder letters improved return rates. Thus, both physicians and mammography facilities should be encouraged to institutionalize these strategies.

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## APPENDIX E

Manuscript – Rates and Correlates Associated with Mammography

**Rates and Correlates of Discomfort Associated with Mammography**

Joanna R. Dillum, M.P.H., Elizabeth C. Lewis, M.P.H., and Joni A. Mayer, Ph.D.

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**Running Head:** Mammography Discomfort

**Abstract:** 155 Words

**Text:** 3,146 Words

**Tables:** 3

**Figures:** 1

This study was funded by the U.S. Army Medical Research and Materiel Command under DAMD-17-94-J-4360. The contents of the paper do not necessarily reflect the position or the policy of the government, and no official endorsement should be inferred.

This paper has not been presented at an RSNA meeting nor has it been submitted for presentation at a future RSNA meeting.

**Rates and Correlates of Discomfort Associated with Mammography**

### **Author Contributions**

Guarantor of integrity of the entire study: Joni Mayer

Study concepts: Joni Mayer, Joanna Dullum

Study design: Joni Mayer

Definition of intellectual content: Joni Mayer, Joanna Dullum

Literature research: Joanna Dullum, Elizabeth Lewis

Clinical studies: Not applicable

Experimental studies: Joni Mayer

Data acquisition: Elizabeth Lewis

Data analysis: Joanna Dullum, Joni Mayer

Statistical analysis: Joanna Dullum, Joni Mayer

Manuscript preparation: Joanna Dullum, Elizabeth Lewis, Joni Mayer

Manuscript editing: Joni Mayer

Manuscript review: Joni Mayer

## **Abstract**

*Purpose.* To explore the rates and correlates of mammography discomfort in asymptomatic women, aged 50-74 years, from six San Diego mammography facilities.

*Materials and Methods.* Subjects (N=1800) completed a 43-item telephone interview approximately 3 weeks after obtaining a screening mammogram. Bivariate associations between variables were analyzed using chi square analysis. Logistic regression was used to assess the independent predictors of mammography discomfort while controlling for all other factors.

*Results.* Nine hundred thirty-three (52%) of the women surveyed reported moderate to extreme discomfort with the mammogram. Discomfort was not related to intentions to have a future mammogram ( $p=0.95$ ). Factors that were significantly associated with discomfort in multivariate analyses were facility ( $p<0.0001$ ), satisfaction with care ( $p<0.04$ ), and perception of the technologist's "roughness" ( $p<0.0001$ ).

*Conclusions.* Discomfort, although not related to future mammogram intentions, had a relatively high prevalence. Future research should explore the effects of discomfort on facility loyalty and identify the specific facility-based factors that predict discomfort.

*Key Words:* Breast, Breast Radiography, Cancer Screening

## Introduction

Regular mammography screening can decrease mortality in women aged 50 to 74 years by approximately 26% [1]. Additionally, results from a recent meta-analysis of studies that included an average of 12.7 years of follow-up data indicated that mammography significantly decreased mortality (by approximately 18%) in women aged 40-49 [2]. Therefore, major health organizations such as the American Cancer Society recommend that women 40 years and older obtain yearly mammograms. Despite the potential benefits, the majority of women over 40 years do not have mammograms on a regular basis [3].

The mammography procedure involves a fairly tight compression of the breast in order to obtain a good image. Several previous studies have assessed patients' perceptions of this compression [4-17]. Of the studies that have assessed mammography-related discomfort, findings have been variable with respect to the distributions of discomfort. The variability may be due, in part, to methodological differences across the studies. For example, the rating scales used have varied with respect to assessing "discomfort," "pain," or a combination of these two constructs. Nevertheless, taken as a whole, the results from previous research suggest that a substantial proportion of women experience at least some physical discomfort during mammography.

In this article, rates of physical discomfort associated with mammography among women attending six San Diego County mammography facilities are presented.

Additionally, potential correlates of mammography discomfort were examined. Although no formal hypotheses were tested, the choice of potential correlates was guided by previous literature.

## **Materials and Methods**

### *Setting and Subjects*

Subjects in the present study (N=1,800) were recruited to participate in a larger controlled trial, the Picture of Health Mammography Project. The goal of the intervention being evaluated in the trial is to increase adherence to mammography screening guidelines among women 50-74 years. The endpoint is whether the subject has a mammogram within 12-14 months after the study entry mammogram.

The study was conducted at six San Diego County mammography facilities. At the time of the study, the participating facilities were performing an estimated average of 2,508 screening mammograms per facility per year for women ages 50-74. Following recruitment of the six facilities, each facility's staff identified up to 31 of the physicians who referred the most number of patients to that facility for screening mammograms. A total of 160 physicians were asked to participate; 82(51%) agreed. Participating physicians gave blanket permission for project and/or mammography facility staff to seek consent from his/her patients who met study inclusion criteria. Inclusion criteria for the



subjects included: being 50 -74 years, obtaining negative results for the study entry mammogram, Spanish or English speaking, no personal history of breast cancer, asymptomatic at the time of study entry mammogram, and having a participating primary care physician. Participation involved a telephone interview administered by a professional research firm. The interview was conducted prior to randomization in the trial. Written informed consent was obtained after the study was explained fully in an informational packet and at times, in-person. The study was approved by the Committee on the Protection of Human Subjects at San Diego State University.

### *Measures*

Data were collected from 1995-1997 via a 43-item telephone interview, with 11 of the items explored in this study. The 11 items were: perceived discomfort from the mammogram, satisfaction with the care received while obtaining the study entry mammogram (3 items), intentions to obtain a mammogram the following year, number of prior mammograms, fibrocystic breast status, age, education, ethnicity, and income.

The discomfort scale was adapted from Stomper et al. [16]. Although the original scale included levels of both discomfort and pain, our version included only levels of discomfort (no, slight, moderate, substantial, and extreme physical discomfort).

Specifically, the subject was asked "I want you to think about the mammogram you had most recently. When the mammography equipment was pressing against your breasts during the X-ray, how did you feel?" The 3 satisfaction items were adapted from the

26-item breast screening satisfaction scale of Cockburn et al. [18]. The respondent was asked to rate her level of agreement (1=strongly disagree; 5=strongly agree) with the statements: a) "I was very satisfied with the care I received," b) "I feel confident that the mammogram was taken properly," and c) "The person was too rough when taking the mammogram." For the intentions item, subjects rated their likelihood (on a 5-point Likert scale) that they would "have another routine screening mammogram next year, even if your doctor does not suggest one." This item was adapted from Mayer et al. [19]. The items assessing demographic characteristics were adapted from the National Cancer Institute Breast Cancer Screening Consortium's survey [20] and the items assessing fibrocystic breast status and screening history were developed by our research team for this study. Two additional variables were included in analysis: facility at which the mammogram was obtained and time interval between the mammogram and the interview.

Interviewers attempted to reach subjects as soon as possible following the study entry mammogram and completion of informed consent procedures. Up to 20 attempts were made to contact subjects for the interview before considering them as "unreachable" (most respondents were reached within 1-3 attempts). The interview was an average of 14 minutes long and was conducted a median of 3 weeks after the mammogram.

### *Analysis*

The data were analyzed using the Statistical Package for the Social Sciences (SPSS, Inc., 1995). Frequencies for all variables were generated and bivariate associations

between variables were analyzed using chi square analyses. Logistic regression was used to assess the independent predictors of mammography discomfort while controlling for all other factors.

## **Results**

### *Response Rate*

Graduate assistants used mammography facility schedules to identify all women meeting study inclusion criteria during the recruitment phase of the study. A total of 3,701 women were identified as eligible and were asked to participate in the study. One thousand eight hundred sixty-three (50%) of the 3,701 women approached enrolled in the study. Sixty three of the 1,863 did not complete the telephone interview for the following reasons: could not be contacted within the 20 attempts (n=33), refused to participate in the interview when they were phoned (n=18), wrong telephone number (n=4), telephone interview was incomplete (n=4), telephone number was disconnected (n=3), or had limited English skills and spoke no Spanish (n=1). Thus, data for 1,800 subjects were available for this analysis.

### *Sample Characteristics and Descriptive Data*

Demographic and selected health-related information for the study sample is provided in Table 1. The mean age was 60 years (SD = 7.4). The majority of the sample were non-Hispanic white and had relatively high education and income levels. Approximately 32%

had been told they had fibrocystic breast disease. The number of subjects reporting multiple previous mammograms was high.

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Insert Table 1 About Here

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As shown in the figure, 52% of the sample reported moderate physical discomfort or greater when the mammography equipment was pressing against the breasts. As shown in Table 2, the reported likelihood that a subject would return next year for a mammogram even if her doctor did not recommend one was high. When questioned regarding the overall satisfaction of care they received, the majority of the subjects reported being very satisfied. Most were very confident that the mammogram was taken properly and did not think that the technologist was too rough when taking the mammogram.

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Insert Figure 1 and Table 2 About Here

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#### *Associations Between Discomfort and Selected Variables*

Table 3 presents the proportions of subjects reporting "moderate" or higher levels of discomfort, by categories of various factors, along with the results of chi square analyses.

Moderate-to-higher levels of discomfort (vs. no or slight discomfort levels) were prevalent significantly more often in subjects having: higher (vs. lower) income levels, higher education levels, fibrocystic breasts, less than strong satisfaction with the care received during the mammogram, less than a strong level of confidence that the mammogram was taken properly, and stronger (vs. weaker) agreement that the technologist was "too rough." The sample sizes for ethnic/racial groups, with the exception of non-Latina whites, were relatively small. Nevertheless, the rates of discomfort between whites, Latinas, and the combination of all other groups were compared and the association was significant, with Latinas reporting the lowest rates of at-least-moderate discomfort. Finally, the association between facility and discomfort was significant, with the level of at-least-moderate discomfort ranging from 38% to 66%. Factors that were not significantly associated with discomfort in bivariate analysis included age, number of previous mammograms, interval between the mammogram and the interview, and intentions to have a future mammogram.

In an exploratory manner, chi square tests of the association between discomfort level and intentions were conducted using two other dichotomous coding schemes for the discomfort variable: a) none-to-moderate versus substantial/extreme and b) none-to-substantial versus extreme. The distributions resulting from these tests were comparable to each other and to the primary test presented in Table 3. The associations in the new tests were not statistically significant.

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Insert Table 3 About Here

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Each of the variables that had been included in the bivariate tests was entered simultaneously in a logistic regression analysis, with discomfort (0 = none or slight; 1 = moderate, substantial, or extreme) as the dependent variable. There were approximately 48% (867/1800) and 52% (933/1800) of the sample in these respective categories. The only variables that significantly predicted discomfort in the logistic regression model were facility ( $p < 0.0001$ ), satisfaction with care ( $p < 0.04$ ), and belief that the technologist was too rough ( $p < 0.0001$ ).

### Discussion

This paper addresses the prevalence and correlates of mammography discomfort in a sample of older women with a history of high mammography compliance. The distribution of reported discomfort was none (12%), slight (36%), moderate (32%), substantial (16%), and extreme (5%). Stomper et al. [16], in a large ( $N=1847$ ), multi-center survey on mammography discomfort/pain, found that only 1% of their sample reported pain, and that the levels of discomfort were: none (49%), mild (39%), moderate (9%), and severe (1%). Thus, the reported levels in that study were substantially lower than those found in the present study. As discussed in a recent review paper [21], a

multitude of methodological differences may explain the discrepant results between these two studies, and across the other studies published to date. For example, compared to the Stomper et al study, our sample: was older (mean = 60 vs. 50 years), had higher rates of having a previous mammogram (98% vs. 63%), were assessed via phone interview days to weeks after the mammogram (vs. paper-and-pencil form immediately after), and were presented with a scale assessing discomfort only (vs. a scale containing both discomfort and pain).

Eight of the 12 possible correlates of discomfort that were tested using bivariate analysis showed significant associations. However, when these same 12 variables simultaneously were included in a logistic regression analysis, only three remained as statistically significant. These variables were facility (at which higher discomfort levels ranged from 38% to 66%), overall satisfaction with the care received, and perception that the technologist was too rough. Stomper et al. [16] also found that facility independently predicted reported discomfort. Using a similar dichotomization of discomfort level, their seven facilities ranged from 5% to 22% on moderate or higher discomfort. They hypothesized that the variation in technologists was one of the reasons the facilities differed on discomfort ratings. The facility-based differences found in our study may have been due to technologist characteristics, as well as differences in facility ambiance. For example, the facility at which the lowest discomfort level was reported provided each patient with a fresh rose after her mammogram. However, from existing data, we are

unable to determine the actual contributions of this and other amenities to patients' perceptions.

The significant relationships between discomfort and both satisfaction with care and rating of the technologists' "roughness" were not surprising. However, given the study design, no causality should be inferred. In contrast, Cockburn et al. [8] found no relationship between discomfort and the roughness variable.

An initially surprising finding was the lack of a significant association between discomfort and intentions to have a mammogram in the future. However, it may be explained by the lack of variability in our intentions variable; approximately 79% of our sample reported they were very likely to have a future mammogram. The mammography history of our sample also suggests that they were highly motivated to obtain mammograms regularly, even if they perceived them to be uncomfortable. Cockburn et al. [8] also found no relationship between discomfort and intentions, but similar to us, had few subjects with low intentions.

Several methodological issues should be considered when interpreting the findings. First, to be eligible for the study, a woman had to have been referred to her study entry mammogram by a participating physician. Because only 51% of the physicians recruited consented to participate and subsequently, only 50% of their patients (who had a screening mammogram at one of the six facilities) consented to participate, limitations to the generalizability of the results must be considered. For example, as noted above, our



sample was relatively adherent with obtaining regular mammograms, which may have been a function of self-selection bias. Thus, the number of barriers to mammography they had (including discomfort) may differ from the barriers of less adherent samples. Future studies of mammography discomfort should select both women who are having mammograms for the first time and those who have a more sporadic, less adherent history. In the current study, refusers were, on average, approximately one year older than consenters ( $p < 0.001$ ; data not presented). Unfortunately, no additional data on refusers were available for a comprehensive comparison.

Second, our interviews were delayed by a median of 3 weeks from when the mammogram was obtained. A more accurate measure of the subject's perceived discomfort level would have been obtained during or immediately after the procedure, with additional (e.g., 3 and 6 month) follow-up assessments. Although we found no relationship between time since mammogram and discomfort level, we are unable to assess whether discomfort perception one day or more after the procedure changed from the initial (at time of mammogram) perception. Cockburn et al. [8] found that subjects changed their discomfort ratings from 1-2 days after to 3 months after the mammogram, with a tendency to report greater discomfort at the 3 month follow-up.

Third, characteristics of the discomfort scale may have influenced our discomfort ratings. For example, in an attempt to insure that respondents rated the physical discomfort they experienced from the compression, we worded the item very specifically

(i.e., “when the mammography equipment was pressing against your breast...”). This may have biased the responses in the direction of reporting greater discomfort.

Additionally, our scale measured only discomfort, and we had no items that asked about “pain.” For the discomfort scale, subjects were not given analogies or examples to define what was meant by the various levels of discomfort response options. Therefore, any conclusions about pain perceptions per se are limited and it is not possible to ascertain whether having response options about only discomfort influenced the scale’s sensitivity. However, a recent study that separately measured mammography pain and discomfort in the same cohort found that the distributions for these two constructs were nearly identical, and the scales were highly correlated ( $r=.67$ ,  $p<0.001$ ) [4]. These data suggest that the constructs are strongly related.

Finally, similar to most of the previous studies on this topic, we do not have data on the degree of compression force of each mammogram. Force may have an important relationship with perceived discomfort. For example, one study found that the amount of force used was significantly associated to the reported level of discomfort/pain [17]. Although adequate compression is essential for a high-quality mammogram, there likely is a level of force above which the added quality is negligible and the discomfort level is unnecessarily high. Sullivan et al. [17] found that high quality mammograms could be obtained with forces less than the maximum available level.

Our study also had several strengths. First, it was the second largest of all eight U.S. studies on this topic and along with the largest study [16], had the only sample exceeding one thousand. Second, it was one of only three that included multiple mammography facilities, which enhances the generalizability of the findings. Third, given our geographic location, we used a variety of strategies to ensure inclusion of Latinas in our sample. Only three previous mammography discomfort studies had reported including any Latinas in their samples [6,12,15]. Fourth, in general the women in our study were older (mean = 60; range = 50-74) than the women in the previous studies (composite mean = 53, with many studies including women in their 30's and 40's). Thus, our sample was at high risk for developing breast cancer and more likely to benefit from annual screening. Focusing on the potential barriers to screening in this age group (relative to younger age groups) therefore is important. Finally, we used a rating scale that attempted to measure only one construct -- discomfort. The validity of the scales used in some of the previous studies was compromised by including two constructs, perceived discomfort and perceived pain, whose relationship is unclear from both measurement and perceptual perspectives [21].

In sum, although this study found a relatively large proportion of women who reported physical discomfort during mammography, discomfort did not appear to have an impact on intentions to have future mammograms. Nevertheless, discomfort may be important to mammography facilities with respect to consumer satisfaction. For example, had we

assessed intentions to return for a mammogram to the same facility, those women with higher discomfort levels may have been more likely to respond negatively.

Future research should: a) investigate samples with greater heterogeneity with respect to mammography history/motivation; b) assess discomfort level in close proximity to the mammogram; c) assess objective characteristics of the pain stimulus, such as compression force, and d) investigate the impact of discomfort on “facility loyalty.”

At three of our six facilities, approximately one-half or more of the respondents reported at least moderate mammography-related discomfort; at one facility, this figure approached two-thirds. Individual mammography facilities should systematically assess patient discomfort level, and monitor exam characteristics (e.g., level of compression) and other variables (e.g., treatment by technologist and receptionist, advance notification that exam may be uncomfortable, etc.). Until additional research-based data become available, the results of facility-specific clinical observations may help equip facility managers with the information needed to reduce patient discomfort.

**Acknowledgments**

We thank Heather Kurata, Angela Holbrook, and Rebecca Lourenco for their excellent subject recruitment and library skills, and Dr. Donald Slymen for providing consultation on the statistical analysis. We are grateful to the staff at the following mammography facilities for their contributions to this study: The Lybrand Mammography and Education Center, Scripps Memorial Hospital; Center for Women's Health, University of California at San Diego; Alvarado Breast Center; Mercy Women's Imaging Center, Mercy Hospital; Scripps South Bay Imaging; and Tri-City Outpatient Imaging Center, Tri-City Medical Center. Lester Greenberg and his staff at Luth Research provided outstanding expertise in conducting the interviews and managing the interview data.

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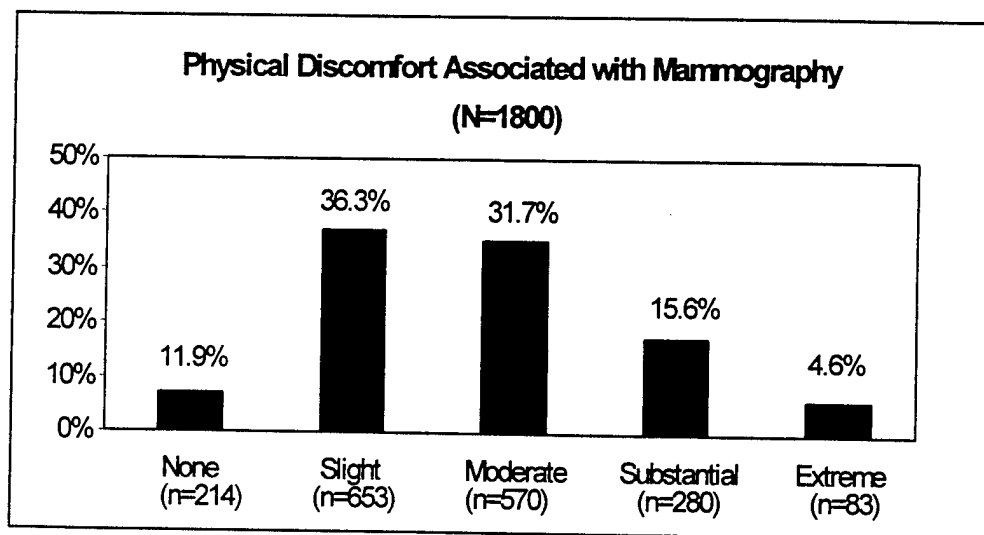
Caption for Figure 1

Approximately one-half of the sample reported at least a moderate level of discomfort associated with their recent mammogram.

Figure 1

Mammography Discomfort

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Approximately one-half of the sample reported at least a moderate level of discomfort associated with their recent mammogram.

Table 1

Characteristics of the Sample (N = 1800)

Characteristic	N <sup>a</sup>	%
Age		
50-64	1205	66.9
65-74	595	33.1
Ethnicity		
White, non-Latina	1513	84.3
Latina	141	7.9
African American	62	3.5
Asian	27	1.5
American Indian	7	0.4
Pacific Islander	7	0.4
Other	37	2.1
Income		
0 - \$25,000	431	27.5
\$25,001 - \$40,000	448	28.6
Over \$40,000	686	43.8
Education		
High school graduate or below	513	28.6
Some college	657	36.6
College graduate	626	34.9
Has fibrocystic breasts	575	32.4
Number of previous mammograms		
0	35	1.9
1-4	444	24.7
5-7	468	26.0
8-10	453	25.2
11 +	400	22.2

<sup>a</sup> The figures in the columns for ethnicity, income, education, and fibrocystic breasts do not add to 1800 due to missing data.

Table 2

Mammography Intentions and Satisfaction (N=1800)

	N	%
Intentions to have a mammogram next year:		
Very unlikely	82	4.6
Somewhat unlikely	56	3.1
A 50/50 chance	108	6.0
Somewhat likely	133	7.4
Very likely	1421	78.9
Satisfied with care:		
Strongly disagree	11	0.6
Disagree	17	0.9
Neutral	25	1.4
Agree	416	23.1
Strongly agree	1331	73.9
Confident that mammogram was taken properly:		
Strongly disagree	11	0.6
Disagree	6	0.3
Neutral	34	1.9
Agree	443	24.6
Strongly agree	1306	72.6
Thought person was too rough taking the mammogram:		
Strongly disagree	1181	65.6
Disagree	497	27.6
Neutral	44	2.4
Agree	43	2.4
Strongly agree	35	1.9

Table 3

Bivariate Relationships Between Discomfort and Selected Variables (N=1800)

Factor	% With $\geq$ Moderate Discomfort	$\chi^2$	P-Value
Age		3.41	0.06
50-64	53.4 (643/1205)		
60-74	48.7 (290/595)		
Ethnicity		12.17	0.002
White, non-Latina	52.5 (794/1513)		
Latina	38.3 (54/141)		
Other	57.1 (80/140)		
Income		10.58	0.005
0 - \$25,000	50.1 (216/431)		
\$25,001 - \$40,000	48.4 (217/448)		
Over \$40,000	57.4 (394/686)		
Education		10.95	0.004
High school graduate or below	46.0 (236/513)		
Some college	53.1 (349/657)		
College graduate	55.6 (348/626)		
Has fibrocystic breasts		6.70	0.01
Yes	56.3 (324/575)		
No	49.8 (598/1201)		
Number of previous mammograms <sup>a</sup>		3.42	0.33
1-4	48.6 (216/444)		
5-7	53.6 (251/468)		
8-10	54.1 (245/453)		
11+	53.3 (213/400)		

Facility		84.09	0.00001
1	37.7 (154/408)		
2	42.9 (3/7)		
3	44.4 (99/223)		
4	49.2 (229/465)		
5	59.8 (110/184)		
6	65.9 (338/513)		
Intentions to have a mammogram next year <sup>b</sup>		0.004	0.95
Very likely	51.8 (736/1421)		
Other responses	52.0 (197/379)		
Satisfied with care <sup>b</sup>		5.05	0.025
Strongly agree	50.3 (669/1331)		
Other responses	56.3 (264/469)		
Confident that mammogram was taken properly <sup>b</sup>		7.52	0.006
Strongly agree	49.8 (651/1306)		
Other responses	57.1 (282/494)		
Thought person was too rough taking the mammogram <sup>b</sup>		60.24	0.00001
Strongly disagree	45.2 (534/1181)		
Other responses	64.5 (399/619)		
Interval between mammogram and interview <sup>c</sup>		1.33	0.25
3-21 days	50.5 (461/913)		
≥ 22 days	53.2 (472/887)		

<sup>a</sup> Based on those that had at least one previous mammogram, which was 98% of the sample (n=1765).

<sup>b</sup> Responses to these 5-point Likert scales were dichotomized, based on the skewness of the distributions (see Table 2).

<sup>c</sup> Median interval = 21 days.

## APPENDIX F

Manuscript – Patient Reminder Letters to Promote Annual Mammograms: A  
Randomized Controlled Trial

**Patient Reminder Letters to Promote Annual Mammograms:**

**A Randomized Controlled Trial**

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**Abstract:** 180 words

**Tables:** 4

**Text:** 3,098 words



## ABSTRACT

**Background.** This study assessed the effects of a reminder letter from a physician (relative to a mammography facility letter or no letter) on appointment compliance of women 50 - 74 years due for an annual screening mammogram.

**Methods.** A total of 1,562 women were randomly assigned to the groups. Each Group 1 subject received a reminder letter from her physician, Group 2 - a reminder letter from her mammography facility, and Group 3 served as a control group.

**Results.** The return rates for Groups 1, 2, and 3 were 47.7%, 46.6%, and 28.3%, respectively; the overall difference was significant using a Chi-square analysis ( $p < 0.001$ ). Bonferroni pairwise comparisons indicated no difference between Groups 1 and 2 but significant differences ( $p < 0.001$ ) between Group 3 and the other two groups. Logistic regression indicated that relative to Group 3, the odds of returning for Groups 1 and 2 were 2.31 and 2.21, respectively ( $p < 0.001$ ).

**Conclusions.** Mammography providers and their patients likely will benefit from inreach reminder systems. Physicians who do not use reminder systems should refer their patients to facilities that use these systems.

**Key Words:** mammography screening, adherence, randomized controlled trial

## INTRODUCTION

Results from surveys conducted over the past decade indicate that U.S. women ages 50 and older have shown substantial increases in the rates of having had at least one mammogram and in the rates of recent screening.<sup>1-2</sup> Three other trends that have emerged in the mammography compliance literature are: 1) rates of annual screening in this age group continue to be fairly low;<sup>3-8</sup> 2) advice by a physician to have a mammogram is a strong predictor of adherence to regular mammography;<sup>3,9-12</sup> and 3) reminder letters appear to be successful in promoting general mammography appointment adherence<sup>13</sup> but their efficacy with annual return mammograms has not been studied widely.

Mammography screening at regular intervals involves an interplay between the primary (or referring) physician, the patient, and the mammography provider.<sup>14</sup> From the mammography provider's perspective, high annual return rates are desirable economically.<sup>15</sup> Mailed appointment reminders are routinely used as an inreach strategy by mammography facilities.<sup>16</sup>

In an earlier controlled pilot study (N = 63), our research group evaluated the effects of a reminder letter from a physician on the compliance of women to their annual mammography appointment.<sup>17</sup> A novel aspect of the intervention strategy was that the letter, although on the letterhead stationery of the physician of each woman, actually was generated and mailed by the mammography facility. This procedure was used to minimize the burden on physicians. Compared to control subjects, intervention subjects had significantly higher return rates (47% vs. 19%). A nonrandomized comparison group from the same facility had a 26% return rate.

The present study tested these interventions on a larger scale. To our knowledge, other than our pilot study mentioned above<sup>17</sup>, it is the only randomized controlled trial to assess the effects of physician reminders (or advice) on mammography interval adherence. Other strengths and/or innovations included using multiple mammography facilities and a large sample of subjects, testing interventions that have a high potential for institutionalization, and using an objective strategy to measure outcome. It was hypothesized that 1) both physician reminders and facility reminders would produce higher mammography return rates than no reminders and 2) physician reminders would produce higher rates than facility reminders.

## **METHODS**

### **Human Subjects Approvals**

All study procedures received approval by the Committee on the Protection of Human Subjects of San Diego State University and by the Human Use Review and Regulatory Affairs Division of the funding agency (U.S. Army Medical Research and Materiel Command). Additionally, for the participating mammography facilities that had institutional review boards (IRBs), approvals were obtained from these IRBs.

### **Settings and Subjects**

Recruitment for this study involved three tiers: mammography facilities, physicians referring patients to those facilities, and patients who were referred to the participating facilities by the participating physicians. Inclusion criteria for facilities were: 1) the patient volume could accommodate approximately one-sixth

of the sample; 2) an accurate and efficient computerized or manual record keeping system; 3) the personnel at the facility agreed to follow study protocol; 4) the facility was certified by the California Department of Health Services Radiologic Health Branch and accredited by the American College of Radiology and the Food and Drug Administration; 5) the facility used a fee-for-service model; and 6) the facility had been in business for at least one year prior to the study's onset.

Following recruitment of the six facilities, each facility's staff identified up to 31 of the physicians who referred the most number of patients to that facility for screening mammograms. Project staff sent these physicians a packet containing an introductory cover letter, letter of support from the facility medical director, pilot study results, a sample of the physician letter, and a chart stating responsibilities of participating physicians and the project staff. In each packet was a pre-addressed stamped envelope and form to be signed indicating the physician's participation. Follow-up calls were made until a response from each physician was obtained.

Physicians were encouraged not to modify their patient recall or referral patterns during the course of the study, nor to discuss the study with their patients. They were told they were providing a blanket consent that potentially covered any of their referred patients who met the other inclusion criteria. During physician recruitment, we reassured physicians that the control group would receive a reminder delayed by only 2 months. After a physician was recruited, project staff acquired the physician's stationery. During the subject recruitment phase, every few months physicians were sent a list of their patients participating in the study.

Subsequently, the study recruited subjects from the women who were referred to one of the six facilities for a screening mammogram by a participating physician and received this study entry mammogram. Additional inclusion criteria were: 1) age 50-74 (at the time of entry mammogram); 2) no history of breast cancer; 3) negative test results for entry mammogram; 4) consented to participate; and 5) spoke either English or Spanish. Subjects who were participating in the clinical arms of the Women's Health Initiative were excluded from the present study.

Recruitment of consecutive eligible subjects was conducted in monthly waves over a 23-month period, June 1995 through April 1997. Subjects were recruited and written consent obtained near the time of the initial (entry) mammogram. Prior to this appointment, the appointment schedule containing information about inclusion criteria (e.g., participating physician, age, no breast cancer history) was highlighted. Research assistants attempted to reach all eligible subjects by phone and/or mail before their appointments to explain the project.

Subjects consented to participate in the study as a whole, including the phone survey, random assignment to study conditions, and monitoring of mammography adherence. Women who refused survey participation at the time of the interview were dropped as subjects. For those subjects who preferred Spanish, the project provided Spanish language materials and a bilingual interviewer. Within several days following consent, subjects were contacted by phone by a professional female interviewer, who elicited information about subject characteristics.

Compliance was defined as having the target (outcome) mammogram 12-14 months after the study entry mammogram. At 11 months after the study entry mammogram for a given wave of subjects, subjects (within referring physician within facility) were randomly assigned to one of the three study groups. Blocked randomization was used to ensure approximately equal numbers of subjects were assigned to each group within physician. Physicians and facilities were masked with respect to the randomized assignments of all subjects.

### **Intervention**

The intervention was implemented in monthly waves. The month of the subject's study entry mammogram was designated as the first month of the 60-day target interval, irrespective of what day of the month the initial appointment occurred. Reminders were timed to arrive on day 1 of the first target month. Subjects in Group 1 (Physician Letter) were mailed the physician reminder letter on the referring physician's letterhead with his/her signature. The letter stated that it had been a year since the last mammogram, encouraged the patient to call her physician to schedule a clinical breast exam and obtain a mammography referral, encouraged the patient to call for a mammography appointment, and provided the facility's name and phone number. Project staff, who previously had obtained the stationery, produced and mailed these letters.

Subjects in Group 2 (Facility Letter) were mailed a letter with content similar to that of the physician letter, but on the letterhead of the facility at which the study entry mammogram was obtained. There was no signature at the end of this letter; the name of the facility was type-written. Project staff were responsible for

producing and mailing these letters. Subjects in Group 3 (Control) were mailed no reminder letters until the outcome monitoring period (2 months) ended. At that point, they received a facility reminder letter. During the study, project staff monitored the facilities and physicians who used reminder systems to ensure they refrained from mailing these reminders to study participants; five facilities had a mailed reminder system at study entry.

### **Outcome Measure**

The dependent variable, mammography compliance, was operationalized as having a screening mammogram during a 60-day interval; day 1 of this interval was the first day of the month of the study entry mammogram. Appointment status of subjects during this interval was assessed using facility appointment records. Appointment records also were used to determine if any subjects scheduled an appointment prior to the intervention date for either a screening or diagnostic mammogram; these subjects' data were deleted from the analysis. Adherence was coded dichotomously (yes, no) and required that the appointment be completed (i.e., both scheduled and kept) during the 60-day interval.

Sample size calculations were based on a comparison among the compliance rates with allowance for Bonferonni-adjusted multiple comparisons and used effect sizes from the pilot data.<sup>17</sup> Using an overall significance level of .05, 520 subjects per group were required at the end of the study with 90% power. To account for attrition over the study period, the sample size was inflated by approximately 15% to 620 per group. Therefore, a total sample of 1860 was required. The above calculations assumed pairwise comparisons would be utilized following a finding

that the null hypothesis of no differences among the three rates was rejected based on a chi-square test for analyzing a 3x2 contingency table.<sup>18</sup>

### **Telephone Survey**

Within a median of 3 weeks following the study entry mammogram, subjects were interviewed by phone to obtain data on selected variables. This 43-item survey included items on demographics, provider variables, insurance coverage, breast health history, and screening history. The majority of the items had been used in previously published studies on mammography adherence.

### **Analysis**

All group comparisons were carried out according to the intent-to-treat rule. Baseline comparisons among groups were examined with chi-square tests for categorical variables and a one-way analysis of variance for continuous variables. The unadjusted overall comparison among the groups on mammography adherence rates used a chi-square test for contingency tables followed by multiple comparisons among the groups using the Bonferroni method. Adjustment for selected baseline characteristics and construction of odds ratios along with their 95% confidence intervals were accomplished using logistic regression. SAS version 6.12 was used to implement these analyses.

## **RESULTS**

### **Characteristics of Sample**

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Insert Table 1 About Here

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Table 1 presents selected characteristics of the six mammography facilities. Of the 160 physicians who were asked to participate, 82 (51%) agreed. The most common reasons physicians gave for not participating were time constraints and lack of interest. Of participating physicians, 30% were obstetricians/gynecologists, 28% were internists, 20% were family practitioners, 7% were general practitioners, and 15% were from other specializations.

A total of 3,701 women were identified as eligible and were asked to participate in the study. One thousand eight hundred sixty-three (50%) of the 3,710 women approached enrolled in the study. Three hundred and one of the 1,863 women enrolled were not randomized for the following reasons: enrolled in the Women's Health Initiative ( $n = 118$ ), returned for a mammogram prior to the month due ( $n = 94$ ), subject's physician retired or relocated ( $n = 51$ ), refused the telephone interview after previously enrolling in the study ( $n = 18$ ), other ( $n = 14$ ), and deceased ( $n = 6$ ). Therefore, outcome data were collected for 1,562 subjects.

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Insert Table 2 About Here

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Table 2 presents selected demographic and health-related data, by condition, for the 1,562 subjects who were randomized. The mean ages of subjects in the physician letter, facility letter, and control groups were 60.0 ( $SD = 7.3$ ), 60.5 ( $SD = 7.5$ ), and 60.2 ( $SD = 7.5$ ) years, respectively (n.s.). As noted, the groups did not differ significantly on the key demographic and health-related characteristics that were assessed, suggesting that randomization was successful.

## Outcomes

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Insert Table 3 About Here

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The return rates (i.e., screening adherence) were: physician letter–248/520 (47.7%); facility letter–242/519 (46.6%); and control–148/523 (28.3%). The overall difference among the return rates was significant,  $\chi^2(df=2) = 51.3$ ,  $p<0.001$ . Table 3 displays the Bonferroni pairwise comparisons between the groups. There was no difference between the physician and facility groups. However, both of these groups had significantly higher return rates than the control group.

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Insert Table 4 About Here

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Table 4 examines group differences using logistic regression with and without adjusting for other factors. As shown, the odds ratios changed very little after adjustment. The odds of returning within the 60 day window in either the physician (2.19) or facility letter (2.06) groups were slightly over two times that of the control group after adjustment.

We also examined whether the differences in return rates among intervention groups varied by facility by fitting a model that included the main effects for group and facility and the group by facility interaction (excluding the facility that

contributed 6 subjects). The interaction term was not statistically significant ( $p = 0.45$ ), indicating that the differences among the study groups did not depend on facility. Dropping the interaction term, the main effects model with intervention group and facility did not indicate a significant facility effect ( $p = 0.11$ ), suggesting that return rates did not vary significantly among the facilities.

As noted earlier, following the 60-day follow-up interval, subjects in the control group received a reminder. However, return rate data continued to be collected for an additional 4 months. At 6-months post-intervention, return rates for the remaining evaluable conditions, the physician letter and facility letter groups, were 346/520 (66.5%) and 347/519 (66.9%), respectively, and did not differ from each other,  $\chi^2(1) = .01$ ,  $p = .91$ .

## CONCLUSIONS

The results of this randomized controlled trial indicated that reminders mailed to patients from either their physician or their mammography facility doubled the likelihood that patients would receive a mammogram within 13 months of their previous mammogram relative to patients who received no reminder. The two types of reminders showed no differential effects on outcome at both the 2 and 6 month followups. The pattern of findings persisted after controlling for potential confounders, and was seen within each participating facility.

A previous study that used a randomized 4-group design in a health maintenance organization (HMO) setting compared the effects on mammography compliance of a recommendation letter from each subject's primary care physician

with a recommendation letter from the medical director of the HMO's breast cancer screening program.<sup>19</sup> The compliance rates for these groups were 46% and 47%, respectively (n.s.). The authors questioned whether the lack of effect of the personal physician letters would generalize to fee-for-service practice settings. Our results replicated those of the HMO study both with respect to the actual compliance rates and the lack of differential effects. Women may perceive their primary care physicians, mammography facilities, and HMO-affiliated screening programs as equally credible sources for mammography recommendations (for both initial and repeat mammograms) if they are familiar with the source. To our knowledge, no other mammography compliance studies have compared letters from primary care physicians with letters from a program director or mammography facility director.

A unique feature of our intervention was that it targeted an initially adherent patient's next (i.e., annual) mammogram. Because the previous rate of regular mammography in our sample was found in the baseline survey to be high, we questioned whether this apparently motivated group would benefit from any type of reminder. Yet, over the 60-day follow-up interval, subjects who had received a letter had twice the likelihood of getting a mammogram. Our findings that reminder letters significantly increased mammography compliance relative to no letters were consistent with the findings of a recently published meta-analysis. The author found that of the 11 U.S. studies that compared the effects of mailed patient reminders to no reminders on mammography use, women who received reminders were approximately 50% more likely to get a mammogram.<sup>13</sup>

Several methodological issues related to this study should be addressed.

First, because research staff (rather than staff at physician offices and mammography facilities) mailed the reminder letters, the results of this trial should be interpreted as an indication of the interventions' efficacy (versus effectiveness). Although we do not have data on actual receipt of the letters by the subjects, all subjects in Groups 1 and 2 were mailed letters at the appropriate time. Mailing procedures at physicians' offices and mammography facilities likely show greater variability. Second, some may argue that the 60-day follow-up interval for the study as a whole (all 3 groups) may be too brief. A longer interval would have raised ethical issues specific to withholding "usual care" reminders to women in the delayed treatment control group, given the guidelines of annual mammograms endorsed by many medical/health organizations. Our main results, therefore, must be viewed as relatively "short-term" outcomes. However, from a mammography facility's perspective, the tendency that was found for these letters to have an immediate impact is beneficial with respect to anticipated patient flow and staffing. Also, from the patient's perspective, planning appointments at precise intervals, in conjunction with a birthday, anniversary, etc., may help her remember when she is due for her screening and could work synergistically with a mailed reminder system. There is some evidence that of screened women who obtain a subsequent screening mammogram, the majority do so within 12 to 14<sup>16</sup> or 12 to 13<sup>20</sup> months after the previous mammogram. The benefits of conducting screening in women 50 and older at precise 12-month intervals may be less clear from a disease detection perspective.<sup>21</sup> In contrast, for women age 40 – 49 (who since 1997 have been

included in the screening recommendations of the National Cancer Institute<sup>22</sup>), there is some evidence that screening every year (vs. longer intervals) may increase the sensitivity of mammography, possibly due to rapid tumor growth.<sup>23</sup> Therefore, interventions that promote adherence to fairly precise intervals may be particularly relevant for this younger age group.

Third, self-selection biases may limit the external validity of these findings. The participating fee-for-service facilities, physicians, and patients may not be representative of the available sampling populations of these entities (approximately one-half of the physicians and patients that were approached entered the study). However, the impact of this potential bias on baseline rates of mammography or response to the intervention is unknown. Our results also may only generalize to fee-for-service mammography facilities and patients who are white or Latina. Nevertheless, as noted earlier, our results were consistent with those of Taplin et al.'s<sup>19</sup> HMO-based trial.

As noted above, ours is one of the few studies to have focused on repeat mammograms. More specifically, we selected subjects based on them obtaining a mammogram (at study entry) and followed them prospectively. Furthermore, the content of the intervention letters, as well as the cutoffs used to define adherence, was tailored for an interval adherence trial. Additional strengths included 1) the inclusion of multiple facilities, a fairly large sample of physicians and a large sample of patients; 2) successful randomization of subjects from within referring physicians; 3) the testing of interventions that have a high potential for institutionalization; 4) an 11 to 12 month interval between the interview and receipt of the intervention

letters, in order to minimize potential reactivity of the interview procedure; and  
5) use of an objective measurement strategy for assessing both the study entry  
mammogram and the outcome mammogram.

Our findings have straightforward implications for clinical practice. Primary  
care physicians who do not use patient reminders for promoting regular  
mammography should consider doing so or refer patients to mammography facilities  
that use patient reminder systems. Mammography facilities that use reminders that  
are comparable to those used for Group 2 subjects should continue to implement  
them, given their level of effectiveness found in this study across several facilities.

## ACKNOWLEDGMENTS

This study was funded by the U.S. Army Medical Research and Materiel Command under DAMD-17-94-J-4360. The contents of the paper do not necessarily reflect the position of policy of the government, and no official endorsement should be inferred.

We thank Rebecca Lorenzo and Diane Lee for their excellent subject recruitment and library skills. Charles Lee and Linda Hill provided valuable advice regarding intervention procedures. We are grateful to the following individuals and their staffs for their contributions to this study: Kathy Burns and Patty Werdowatz at The Lybrand Mammography and Education Center, Scripps Memorial Hospital; Linda Olson and Terry Lehmann Wilt at the Center for Women's Health, University of California at San Diego; Louise O'Shaughnessy, Ricci McBurney and Anita LeBrecque at the Alvarado Breast Center; George Ochoa and Cindy Bennett Callen at Mercy Hospital; Lucille Perkins, Bob Romero, and Karen Bianchi at Scripps South Bay Imaging; and John McHargue, Linda Acklin, and Connie George at Tri-City Medical Center. Lester Greenberg and his staff at Luth Research provided outstanding expertise in conducting the interviews and managing the interview data. We thank Robert Langer and Michele Edwards for their assistance in assessing subject eligibility status. Debra Rubio is acknowledged for assistance in manuscript preparation.



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Table 1

Facility Characteristics

Facility	No. Screening Mammograms/day	No. Participating MDs (Consent Rate)	No. Subjects Randomized (Consent Rate)
1	15 - 20	14 (45%)	416 (76%)
2	10 - 15	16 (64%)	408 (62%)
3	20 - 30	12 (48%)	372 (50%)
4	30 - 35	18 (67%)	190 (31%)
5	10 - 15	14 (48%)	170 (54%)
6	5 - 10	8 (35%)	6 (36%)
Total		82 (51%)	1562 (53%)

Table 2

Subject Characteristics

Characteristic	Group 1: Physician Letter (n = 520) % (n)	Group 2: Facility Letter (n = 519) % (n)	Group 3: Control (n = 523) % (n)	p - value
<b>Age Group</b>				0.58
50 - 64	68.9 (358)	65.9 (342)	66.7 (349)	
≥65	31.2 (162)	34.1 (177)	33.3 (174)	
<b>Ethnicity</b>				0.25
White, non-Latina	87.0 (443)	83.8 (423)	83.5 (430)	
Latina	6.5 ( 33)	9.3 ( 47)	7.2 ( 37)	
African American	2.2 ( 11)	3.2 ( 16)	4.3 ( 22)	
Other	4.3 ( 22)	3.8 ( 19)	5.1 ( 26)	
<b>Education</b>				0.20
<8 <sup>th</sup>	2.5 ( 13)	4.0 ( 20)	2.9 ( 15)	
8 - 11	3.9 ( 20)	2.8 ( 14)	4.9 ( 25)	
High school grad	20.5 (105)	22.8 (115)	23.7 (122)	
Post HS, trade	2.5 ( 13)	3.4 ( 17)	4.1 ( 21)	
1 - 3 yrs college	36.7 (188)	33.9 (171)	31.5 (162)	
College grad	14.7 ( 75)	17.1 ( 86)	18.6 ( 96)	
Some grad work	19.1 ( 98)	16.1 ( 81)	14.4 ( 74)	
<b>Family Income (thousands)</b>				0.18
< \$20	20.8 ( 93)	15.1 ( 67)	18.3 ( 80)	
\$20 - 40	35.1 (157)	40.2 (178)	39.8 (174)	
≥ \$40	44.1 (197)	44.7 (198)	41.9 (183)	

Table 2

Subject Characteristics (continued)

Characteristic	Group 1: Physician Letter (n = 520) % (n)	Group 2: Facility Letter (n = 519) % (n)	Group 3: Control (n = 523) % (n)	p - value
<b>Marital Status</b>				0.54
Married	64.1 (325)	64.8 (326)	61.7 (316)	
Widowed	12.6 ( 64)	11.9 ( 60)	14.8 ( 76)	
Divorced/separated	20.3 (103)	20.1 (101)	18.4 ( 94)	
Never married	3.0 ( 15)	3.2 ( 16)	5.1 ( 26)	
<b>Family hx breast cancer</b>	31.1 (156)	25.4 (123)	30.7 (154)	0.09
<b>Type of Insurance</b>				
None	4.7 ( 24)	4.6 ( 23)	4.7 ( 24)	0.95
Medicare only	1.4 ( 7)	1.8 ( 9)	2.1 ( 11)	
No Medicare but other	66.2 (339)	64.6 (326)	66.9 (345)	
Medicare and other	27.7 (142)	29.0 (146)	26.4 (136)	
<b>Number of Previous Mammograms</b>				0.19
0	1.6 ( 8)	2.0 ( 10)	2.9 ( 15)	
1 - 4	26.3 (135)	26.9 (136)	24.8 (128)	
5 - 7	28.3 (145)	24.0 (121)	23.6 (122)	
8 - 10	20.7 (106)	25.9 (131)	27.3 (141)	
11 +	23.2 (119)	21.2 (107)	21.5 (111)	

Table 3

Multiple Comparisons with Bonferroni Adjustment\*

Comparison	Chi-square	p-value
Physician vs. facility	0.12	0.73
Physician vs. control	41.60	<0.001**
Facility vs. control	37.40	<0.001**

\*Each comparison tested at  $0.05/3 = 0.017$  level of significance

\*\*Significant at 0.017 level of significance

Table 4

Logistic Regression Analyses Comparing Groups on the Probability of Returning Within 8 Weeks Unadjusted and Adjusted for Selected Characteristics

	OR	95% Confidence Interval	p-value
<u>Unadjusted</u>			
Control	1.0		
Physician	2.31	1.79 - 2.99	<0.001
Facility	2.21	1.71 - 2.86	<0.001
<u>Adjusted*</u>			
Control	1.0		
Physician	2.19	1.64 - 2.93	<0.001
Facility	2.06	1.54 - 2.76	<0.001

\* Adjusted for age, ethnicity, family history of breast cancer, educational status, marital status, and family income.



APPENDIX G

Participating Physician Questionnaire

Picture of Health Mammography Project  
Participating Physician Questionnaire

Name (Optional): \_\_\_\_\_

Specialization: \_\_\_\_\_

Participating facility(ies) you refer to (check all that apply):

- ☐ Alvarado Breast Center
- ☐ Lybrand Mammography & Education Center
- ☐ Mercy Women's Imaging Center
- ☐ Scripps South Bay Imaging
- ☐ Tri-City Outpatient Imaging Center
- ☐ UCSD Center for Women's Health

First we want to thank you again for your participation in this study - your cooperation was crucial to the success of the project. As we near the end of the study we are interested in hearing your perceptions of the study. In order to help you answer some of the following questions, we'd like to provide you with some general information about the study.

As you know we have been testing a reminder letter we call the "physician-endorsed reminder letter" or "PER". The letter is similar in content to letters many mammography facilities send to remind women about their annual mammograms. The PER is unique because the letter is printed on a woman's referring physician's letterhead and "signed" by her physician (for this project we primarily used signature stamps). Please see the attached sample PER.

At this time we are interested in finding out:

- 1) your perceptions of the PER
- 2) your interest in future research projects

**Perceptions of the PER**

1. Please rate your general level of satisfaction with the PER - the letters that appeared to be coming from you encouraging your patient to have a mammogram? Circle one:

1	2	3	4	5
very	somewhat	neutral	somewhat	very
dissatisfied	dissatisfied		satisfied	satisfied

2. **What were the advantages of the PERs?**  
(check as many as apply):
- ☐ patients like it
  - ☐ helps my relationships with patients
  - ☐ helps my relationship with the mammography facility
  - ☐ encourages patient to schedule an annual exam
  - ☐ encourages patients to return to the mammography facility
  - ☐ saves time for me and my staff
  - ☐ other: please describe \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_
3. **Did your patients comment on the PERs?**  
(check as many as apply):
- ☐ patients mentioned the letters to me
  - ☐ patients mentioned the letters to the appointment scheduler
  - ☐ patients mentioned the letters to the receptionist
  - ☐ patients mentioned the letters to the nurse(s)
4. **If your patients commented on the PERs, please summarize their comments below:**
- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_
5. **What were the disadvantages of the PERs?**  
(check as many as apply):
- ☐ didn't like providing my letterhead
  - ☐ patients don't like it
  - ☐ I would rather send my own reminder
  - ☐ other: please describe \_\_\_\_\_
- \_\_\_\_\_
6. **What suggestions do you have for improving the PERs? Please be specific.**
- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_
7. **Do you currently use any other systematic reminder strategy to facilitate mammography screening (checklist, chart prompt, etc.)?**
- ☐ yes: please describe \_\_\_\_\_
  - ☐ no

**Intentions for the Future**

8. How likely is it that you would continue to participate in this system (mammography facility you refer patients to will send your PER to your patients)? Circle one:

1	2	3	4	5
very unlikely	somewhat unlikely	a 50/50 chance	somewhat likely	very likely

9. Please skip this question if you circled 4 or 5 for question #8 above. If you circled 1, 2, or 3 for question #8, why would you not be likely to participate? Please be specific.

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10. With all other factors (e.g., cost of mammogram, quality, etc.) being equal, would you be more or less likely to refer a patient to a radiology facility that sends PERs (compared to a facility that does not send them)? Check one:

- ☐ more likely  
☐ less likely  
☐ equally likely

11. Would you be interested in collaborating with our research team on similar studies?

- ☐ yes  
☐ no

12. If so, what type(s) of studies would interest/benefit your practice? Please be specific.

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13. Other comments?

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**THANK YOU FOR YOUR TIME AND INTEREST!  
PLEASE RETURN THIS SURVEY IN THE POSTAGE PAID  
ENVELOPE ATTACHED**

## APPENDIX H

### Mammography Facility Staff Survey

Picture of Health Mammography Project  
Mammography Facility Staff Survey

Interviewer: \_\_\_\_\_

Respondent(s): \_\_\_\_\_

Date: \_\_\_\_\_

Facility: \_\_\_\_\_

First we want to thank you again for your cooperation in implementing this study - your help was crucial to the success of the project. As we near the end of the study we are interested in hearing your perceptions of the study and exploring the possibility of incorporating this system into your routine procedures (depending on the results of the study). In order to help you answer some of the following questions, I'd like to provide you with some general information about the study.

As you know we have been testing a unique reminder letter we call the "physician-endorsed reminder letter" or "PER". The letter is similar in content to letters many mammography facilities send to re-call women for their annual mammograms. The PER is unique because the letter is printed on a woman's referring physician's letterhead and "signed" by her physician (for this project we primarily used signature stamps).

**\*\*SHOW SAMPLE PER LETTER**

At your facility we recruited \_\_\_\_\_ physicians and sent the PERs to approximately 1/3 of their patients who consented to be in the study. On average, we prepared \_\_\_\_\_ PERs per month for your facility. Since we used the physicians' actual letterhead we had to print the letters in groups by physician. Next we used a rubber signature stamp to give the appearance that the letter was signed. It took approximately \_\_\_\_\_ hours to generate these letters per month. It may be possible to further streamline these procedures (i.e., use mock physician letterhead, scan physician signatures into computer).

At this time we are interested in finding out :

- 1) your perceptions of the PER
- 2) your current resources for implementing the PER system
- 3) your interest in future research projects

### Perceptions of the PER

1. Did your patients comment on the PERs - the letters that appeared to be coming from the women's physicians encouraging them to have a mammogram?  
☐ yes  
☐ no (Go to #3)
2. If your patients commented on the PERs, what were the nature of their comments?  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_
3. What were your overall impressions of the Picture of Health Mammography project?  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_
4. Did the participating physicians who refer to your facility comment about the PERs or the Picture of Health Mammography Project in general?  
☐ yes  
☐ no (Go to #6)
5. What was the nature of the physician's comments?  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

### Your Resources

6. How many hours do you/your staff currently spend generating reminder letters per month? \_\_\_\_\_
7. How many hours would you/your staff be willing to spend generating reminder letters per month? \_\_\_\_\_
8. (For all facilities except ABC) What type of computer program do you use to manage patient records?  
\_\_\_\_\_

9. Do you currently have software capable of generating reminder letters?

- ☐ yes, the program is: \_\_\_\_\_  
☐ no  
☐ I don't know

10. If you do not have software capable of generating reminder letters, would you be willing to purchase software for this purpose?

- ☐ yes, I would be willing to spend: \_\_\_\_\_  
☐ no

**Intentions for the Future**

11. If the PER letters are found to be significantly more effective than standard facility reminder letters, how likely is it that you would start generating PERs at your facility? Would it be (READ):

- 1=very unlikely  
2=somewhat unlikely  
3=a 50/50 chance  
4=somewhat likely or (Go to #13)  
5=very likely? (Go to #13)

If 1, 2, or 3 above...

12. Why wouldn't your facility be likely to send out the PERs? Please be specific.

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13. How likely is it that your facility would start generating PERs if we provided on-site training and technical assistance? Would it be (READ):

- 1=very unlikely  
2=somewhat unlikely  
3=a 50/50 chance  
4=somewhat likely or  
5=very likely?

14. Would you be interested in collaborating with our research team on similar studies?

- ☐ yes  
☐ no (Go to #16)



**15. If so, what type(s) of studies would interest/benefit your facility? Please be specific.**

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**16. Other comments?**

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## APPENDIX I

Book Chapter – Breast Cancer Screening: Improving Adherence

## Breast Cancer Screening: Improving Adherence

*Joni A. Mayer*

Reprinted from *Behavioral Medicine and Women: A Comprehensive Handbook*, edited by Elaine A. Blechman and Kelly D. Brownell. Copyright 1998 by Guilford Publications, Inc., 72 Spring Street, New York, NY 10012.

**B**reast cancer is a woman's disease; fewer than 1% of the estimated 181,600 cases that will be diagnosed in the United States in 1997 will be men. As the most common cancer and the second leading cause of cancer-related mortality in U.S. women, breast cancer will be responsible for the deaths of 43,900 women in 1997. The lifetime incidence of the disease is currently one in eight.

Commonly accepted risk factors fall into the "nonmodifiable" category and include female gender, increasing age, family history of the disease, earlier menarche, later menopause, and no or delayed childbearing. A recently discovered gene, BRCA1, is highly predictive of breast cancer when a mutation is present. To date, the combined results of prospective observational studies suggest that the relationship between dietary fat intake during adulthood and breast cancer is negligible, although this is a controversial point (for differing views, see the chapters in this volume by Brunner and St. Jeor on nutrition and disease, and by Glanz on nutrition education). Alcohol intake and breast cancer may have a positive association, but this research is in its early stages. Thus, as this book goes to press, few if any scientifically verified primary prevention strategies are available.

### MAMMOGRAPHIC SCREENING: RECOMMENDATIONS AND TRENDS

Because treatment of breast cancer at its earliest stages offers women the best chances for survival, promoting early detection through screening has been a top priority of cancer control specialists. Screening includes mammography, clinical breast exam, and breast self-examination at age-specific intervals; this chapter's focus is on mammography. Encouraging women under age 50 (without additional risk factors) to have regular screening mammograms has been criticized, because clinical trials generally have shown no mortality reductions for ages 40–49 years. (For a fuller discussion of this controversy, see Kaplan's chapter on screening.) In contrast, based on strong scientific evidence, the

majority of health organizations recommend that women 50 and older have regular mammograms; the definition of "regular" ranges from every 12 to every 24 months, depending on the organization. Breast cancer mortality could be reduced by an estimated 30% if all women in this age group obtained regular mammograms. Population-wide screening for women aged 50 and over is justified, because the large majority of breast

**TABLE 34.1.** Possible Approaches to Achieving Annual Mammographic Screening

Approaches	Examples
	<u>Population-oriented</u>
Federal and state laws/ordinances, etc.	Congress passes the Breast and Cervical Cancer Mortality Prevention Act of 1990 (Public Law 101-354); States are awarded grants and matching funds for screening services for underinsured/uninsured women. Some states mandate that insurance policies cover screening at specific intervals.
Policies (e.g., reimbursement, etc.) of health organizations, regulatory agencies, and health care providers	Health maintenance organizations provide screening at specific intervals. Medicare covers (capped) amount for screening at specific intervals. Mammography facilities implement "inreach" strategies that increase their profitability.
Scientific/technological innovations	Tests are developed that identify "high-risk" women, rendering population-wide screening unnecessary. <sup>a</sup> New screening methods are developed that replace existing ones, with higher predictive value, less discomfort, lower costs, etc. <sup>a</sup>
	<u>Individual-oriented</u>
Public education campaigns <sup>b</sup>	American Cancer Society annually sponsors Breast Cancer Awareness Month (e.g., public service announcements, discounts on screenings).
Prompting	Each patient receives reminder for appointment.
Counseling	Woman who has missed several appointments receives phone call from provider; barriers are identified and addressed.
Social influence	Physician discusses screening with patient and refers her. Woman is contacted by a specially trained peer in her social network who encourages participation in screening.
Positive reinforcement/incentive systems	Woman receives gift from the mammography facility after receiving her annual mammogram.

<sup>a</sup>Hypothetical.

<sup>b</sup>Also may be conceptualized as population-oriented.

cancer cases would be missed if only "high-risk" women were targeted. For example, only a small proportion of women with breast cancer report any family history of the disease, and the BRCA1 gene may account for fewer than 5% of all breast cancer cases.

U.S. women aged 50 and older have shown substantial increases in the past 10 years in the rates of having had one mammogram, and in the rates of recent screening. Three trends that emerge with consistency are as follows: (1) Rates of annual screening continue to be fairly low; (2) beyond age 50, screening adherence and age are inversely related (whereas breast cancer and age are positively related); and (3) referral for mammography by a physician is a strong predictor of adherence to regular mammography. These trends are addressed below.

### APPROACHING THE ADHERENCE PROBLEM

In 1989 Robert Jeffery lucidly contrasted population-oriented and individual-oriented strategies for defining and solving public health problems, and recommended a combined approach. The need to integrate these "levels" of interventions is particularly relevant to the issue of promoting adherence to regular mammographic screening. Table 34.1 illustrates selected discrete approaches, categorized according to population versus individual orientation. The population-oriented approaches generally involve something other than the individual woman in the intervention *per se*, even though changes in mammography-obtaining behavior may be the desired outcome. This type of approach may be more likely to change the societal norm or climate, or the context in which individuals behave. The individual approaches generally intervene directly with individuals or groups, attempting to modify knowledge, attitudes, and behaviors.

Mammographic screening at regular intervals involves an interplay among the primary (or referring) physician, the patient, and the mammography provider. Both physicians and mammography providers have various motives (e.g., ethical, quality-of-care, financial) for promoting annual screening of patients. This interplay occurs in an ever-changing context of policies and laws, which influence screening guidelines for women, quality assurance guidelines for providers, and reimbursement opportunities and restrictions. The topics and examples in Table 34.1 and the discussion below are in no way exhaustive, but I hope that they will promote brainstorming of additional intervention and research ideas.

Combining population- and individual-oriented strategies may serve to strengthen an intervention. In fact, one type of strategy alone may be futile in certain situations. For example, following the passage of a law in California mandating that insurance policies cover screening mammograms in accordance with American Cancer Society age guidelines (e.g., annually for women 50 and over), a survey indicated that many women who had the coverage were not aware that they had it. This deficit indicated the need for educational campaigns specific to the new benefit. Likewise, educating women about and motivating them for regular screening (individual-oriented strategies) in the absence of available, affordable screening services (population-oriented strategies) would also be impractical, as well as unethical.

A second example that combines approaches is an "inreach" program with mammography facilities to promote annual mammograms among women 50 and older. The program, which is part of my own research, is based on the following premises. First, in

an urban area, facilities are highly competitive; maintaining high levels of annual return rates among current patients is economically desirable. Second, many facilities routinely use mailed reminder systems; this method of intervention is acceptable to them. Third, physician involvement in achieving mammography adherence is important, probably because of the physician's roles as gatekeeper to the services and as a credible, influential advisor. However, many physicians do not make referrals at the recommended intervals, even though they may endorse the guidelines.

Our current study is comparing the effects of a physician reminder, a facility reminder, and no reminder on annual return rates. The burden on physicians is minimized by the mammography facilities; physicians give the facilities a supply of their letterhead stationery and signature stamps. To date, approximately half of the referring physicians associated with the initial four participating facilities have joined the program. In a pilot study, physicians were pleased with the system, and the physician reminder produced significantly higher return rates than no reminder. Outcome data from the current study will be available in 1998. The system, if successful, has the potential (1) to allow a mammography facility to provide a service to a referring physician; (2) to strengthen the link between the facility and the physician; and (3) to remind each patient to schedule her appointment. From a health perspective, the patient's appointment adherence is of course the most important outcome. Nevertheless, the first and second outcomes may help ensure that the program will be institutionalized and maintained. In fact, an increase in the probability of institutionalization is a major advantage of combining population- and individual-oriented approaches, both within and outside of the breast cancer screening arena.

### **AN IMPORTANT ROLE FOR BEHAVIORAL SCIENCE**

Behavioral medicine practitioners and researchers, particularly those trained as clinical psychologists, are likely to be more comfortable in working with clinical (or high-risk) populations, using individual-oriented intervention approaches. However, in the area of mammography adherence, there is still a great need to work with the general population and to incorporate population-oriented approaches. Behavioral medicine specialists have contributed much to the understanding and promotion of breast cancer screening adherence. Areas still needing further investigation with this expertise, to name a few, are (1) factors associated with low referral rates by physicians of healthy elderly women; (2) patient-based factors associated with low adherence rates of elderly women; and (3) interventions that reduce or offset the punishing consequences of mammograms. But, to reiterate, individual-oriented interventions resulting from these lines of inquiry should be consolidated with population-oriented strategies.

### **ACKNOWLEDGMENT**

Preparation of this chapter was supported, in part, by the U.S. Army Medical Research and Materiel Command under DAMD-17-94-J-4360. The contents of the chapter do not necessarily reflect the position or the policy of the government, and no official endorsement should be inferred.

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## XII. PERSONNEL WHO RECEIVED PAY FROM THE RESEARCH EFFORT

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